

<h2 style="margin: 0;">Regulatory Analysis Form</h2> <p style="margin: 0;">(Completed by Promulgating Agency)</p> <p style="margin: 0;"><i>(All Comments submitted on this regulation will appear on IRRC's website)</i></p>		<p style="margin: 0;">INDEPENDENT REGULATORY REVIEW COMMISSION</p> <h1 style="margin: 0;">RECEIVED</h1> <p style="margin: 0;">SEP 27 2022</p> <p style="margin: 0;">Independent Regulatory Review Commission</p> <p style="margin: 0;">IRRC Number:</p>
<p>(1) Agency Department of Health</p>		
<p>(2) Agency Number: 10 Identification Number: 223</p>		
<p>(3) PA Code Cite: 28 Pa. Code §§ 201.12—201.17, 201.22, 209.1, 209.7, 209.8 and 211.1</p>		
<p>(4) Short Title:</p> <p>Long-term care nursing facilities: <i>Rulemaking 3 – Applications for Ownership, Management and Changes of Ownership; Health and Safety</i></p> <p>Please note that this is the third of four final-form rulemaking packages, with respect to long-term care nursing facilities, to be promulgated by the Department.</p>		
<p>(5) Agency Contacts (List Telephone Number and Email Address):</p> <p>Primary Contact: Ann Chronister, Director, Bureau of Long-Term Care Programs, 717-547-3131, RA-DHLTCRegs@pa.gov</p>		
<p>(6) Type of Rulemaking (check applicable box):</p> <p><input type="checkbox"/> Proposed Regulation</p> <p><input checked="" type="checkbox"/> Final Regulation</p> <p><input type="checkbox"/> Final Omitted Regulation</p>		<p><input type="checkbox"/> Emergency Certification Regulation;</p> <p><input type="checkbox"/> Certification by the Governor</p> <p><input type="checkbox"/> Certification by the Attorney General</p>
<p>(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)</p> <p>This is the third of four rulemaking packages that amend Subpart C (relating to long-term care facilities) of Part IV of Title 28 of the Pennsylvania Code. Subpart C consists of 6 different chapters: Chapters 201, 203, 205, 207, 209 and 211. This final-form rulemaking amends provisions related to applications for ownership, management and changes in ownership, and health and safety, under Chapters 201, 209, and 211.</p> <p>The purpose of this final-form rulemaking is to create consistency between Federal and State requirements for long-term care nursing facilities by updating and eliminating provisions that are outdated and duplicative of the Federal requirements to include the requirements set forth at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities). This final-form rulemaking also updates: (1) State requirements for applications for licensure and ownership of a facility; and (2) responsibilities for licensees, including a quarterly facility assessment.</p>		

(8) State the statutory authority for the regulation. Include specific statutory citation.

Sections 601 and 803 of the Health Care Facilities Act (HCFA or act) (35 P.S. §§ 448.601 and 448.803) authorize the Department to promulgate, after consultation with the Health Policy Board, regulations necessary to carry out the purposes and provisions of the HCFA. Section 801.1 of the HCFA (35 P.S. § 448.801a) seeks to promote the public health and welfare through the establishment of regulations setting minimum standards for the operation of health care facilities. The minimum standards are to assure safe, adequate and efficient facilities and services and to promote the health, safety and adequate care of patients or residents of those facilities. In section 102 of the HCFA, the General Assembly has found that a purpose of the HCFA is, among other things, to assure that citizens receive humane, courteous and dignified treatment. 35 P.S. § 448.102. Finally, Section 201(12) of the HCFA (35 P.S. § 448.201(12)) provides the Department with explicit authority to enforce its rules and regulations promulgated under the HCFA.

The Department also has the duty to protect the health of the people of this Commonwealth under section 2102(a) of the Administrative Code of 1929 (71 P.S. § 532(a)). The Department has general authority to promulgate regulations under section 2102(g) of the Administrative Code of 1929 (71 P.S. § 532(g)) for this purpose.

(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

The regulations are not mandated by any Federal or State statute, court order, or Federal regulation. With respect to State law, the Department is authorized under the HCFA to promulgate regulations that promote the health, safety and adequate care of patients and residents in health care facilities, which includes residents in long-term care nursing facilities. 35 P.S. §§ 448.604 and 448.803. In addition, the act states that the Department shall take into consideration Federal certification standards, as appropriate, when developing rules and regulations for licensure of health care facilities. 35 P.S. § 448.806(b).

The Department's expansion of its adoption of the Federal health and safety requirements for long-term care facilities at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities) in Rulemaking 1 – *General Applicability and Definitions* complies with this requirement.

(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

The percentage of adults aged 65 or older in Pennsylvania is increasing. In 2010, approximately 15% of Pennsylvanians were aged 65 or older. In 2017, this number increased to 17.8%. In 2020, just under 20 percent of the population in Pennsylvania was 65 years of age or older. For every 10 individuals under 25 years of age lost in Pennsylvania since 2010, the state gained 21 persons aged 65 or older. The Commonwealth also has a higher percentage of older adults when compared to other states. In 2017, this Commonwealth ranked fifth in the Nation in the number (2.2 million) of older adults and seventh in percentage (17.8%). The increase in older Pennsylvanians is expected to continue. It has been estimated that by 2030, there will be 38 older Pennsylvanians (65 years of age or older) for every 100-working age Pennsylvanians (15 years of age to 64 years of age). Penn State Harrisburg, Pennsylvania State Data Center. (July 2018). Population Characteristics and Change: 2010 to 2017 (Research Brief). Retrieved from <https://pasdc.hbg.psu.edu/data/research-briefs/pa-population-estimates>; Penn State Harrisburg, Pennsylvania State Data Center. (July 2018). (June 2022). Trends in Pennsylvania's Population by Age. (Research Brief). Retrieved from https://pasdc.hbg.psu.edu/sdc/pasdc_files/researchbriefs/June_2022.pdf.

As the number of older Pennsylvanians increases, the number of those needing long-term care nursing will also increase. It has been estimated that an individual turning 65 years of age today has an almost 70% chance of needing some type of long-term services or support during the remainder of their lifetime; 20% will need long-term care support for longer than 5 years. More people use long-term care services at home and for longer; however, approximately 35% utilize nursing facilities for this type of care. Administration for Community Living. (February 2020). How Much Care Will You Need? Retrieved from <https://acl.gov/ltc/basic-needs/how-much-care-will-you-need>.

Further, the COVID-19 pandemic highlighted the vulnerability of older adults, with a larger percentage of deaths occurring in individuals 65 years of age and older. Centers for Disease Control and Prevention (CDC). Demographic Trends of COVID-19 Cases and Deaths in the US Reported to CDC. Retrieved from <https://covid.cdc.gov/covid-data-tracker/#demographics>. See also, CDC. COVID-19 Weekly Cases and Deaths per 100,000 Population by Age, Race/Ethnicity and Sex, United States, March 1, 2020—June 25, 2022. Retrieved from <https://covid.cdc.gov/covid-data-tracker/#demographicsovertime>. Further, it is estimated that at least a quarter of COVID-19 deaths occurred in long-term care nursing facilities. The COVID Tracking Project. (March 2021). Long-Term-Care COVID Tracker. Retrieved from <https://covidtracking.com/nursing-homes-long-term-care-facilities>. In this Commonwealth alone, there have been approximately 11,000 confirmed deaths of residents in long-term care nursing facilities since January 2020. AARP. (June 16, 2022). AARP Nursing Home COVID-19 Dashboard Fact Sheets. Retrieved from <https://www.aarp.org/ppi/issues/caregiving/info-2020/nursing-home-covid-states.html>.

The Department's long-term care nursing facilities regulations have not been updated since 1999, with the last significant update occurring in 1997 after the 1996 amendment to the Health Care Facilities Act (the HCFA or act) (35 P.S. §§ 448.101—448.904b). Since that time, there have been substantial changes in the means of delivering care and providing a safe environment for residents in long-term care nursing facilities, with the pandemic further highlighting the need for change.

Approximately 72,000 individuals reside in the 682 long-term care nursing facilities currently licensed by the Department. These 72,000 individuals, and their family members, will benefit from this final-form regulation. Further, the current residents for the three private pay facilities will benefit with the updated standards from 1998. Since the Department's adoption of the 1998 regulations 23 years ago,

there have been expanded requirements for emergency preparedness; quality assurance and infection control; abuse, neglect and exploitation protections; and admission and discharge protections to ensure the health and safety of residents. These three facilities had a reported, combined census of 79 residents for the Department's 2020-2021 annual report. Department of Health. (2021). Nursing Home Reports. Retrieved from:

<https://www.health.pa.gov/topics/HealthStatistics/HealthFacilities/NursingHomeReports/Pages/nursing-home-reports.aspx>. Pertinent to this rulemaking, residents, and their family members, will benefit from the adoption of the Federal requirements for infection prevention and control and fire safety and emergency preparedness.

Residents, prospective residents, and their family members will also benefit from new and updated requirements related to the application for licensure process. These new and updated provisions will ensure that prospective licensees are properly vetted before assuming ownership of a facility and will provide much needed transparency in the application for licensure process, which will enable residents and their family members to make informed decisions regarding where to go for their care. Residents and their family members, as well as facility employees, will also benefit from the increased oversight of prospective licensees' experience operating facilities and increased analysis of prospective licensees' financial stability.

Residents will also be positively impacted by requirement that a facility perform quarterly facility assessments. Quarterly facility assessments are used to determine what resources are needed to care for residents during both day-to-day operations and emergencies. Further, these assessments provide a timely indication of any systemic problems at a facility and assist with identifying areas for improvement. Specifically, analyzing the resident population every quarter provides a snapshot as to the overall conditions of the residents at that time, including the most common diseases, conditions, and diagnoses during that time period, and if the facility has the appropriate staff and equipment to take care of those residents, particularly if a trend is found among those residents.

Further, the regulated community will benefit from the efficiency of the consistent adoption and application of the Federal requirements for health and safety at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities). The Commonwealth generally will also benefit from the efficiency of Department surveyors applying consistent health and safety standards.

(11) Are there provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

Yes, there are some provisions that are more stringent than Federal standards, as described below.

The Department's amendments to the application for licensure process in §§ 201.12—201.13 are more stringent than Federal standards. Federal regulations require that a long-term care nursing facility be licensed under State or local laws. *See* 42 CFR 483.70(a) (relating to administration). With respect to a change in ownership for a long-term care nursing facility, Federal regulations specify that a facility must provide written notice to the State agency responsible for licensing the facility. The facility must disclose the name and address of each person with an ownership or control interest of five percent or more, whether any of these persons are related to one another, and the name of any other disclosing entity in the past three years in which any of these persons has had an ownership or controlling interest or has held a position as a managing employee. *See* 42 CFR 483.70(k); 42 CFR 420.206 (relating to

disclosure of persons having ownership, financial or control interest); and 42 CFR 455.104 (relating to disclosure by Medicaid providers and fiscal agents: information on ownership and control). Existing § 201.12 contains similar disclosure requirements to the Federal regulations.

The Department has seen a shift in ownership of long-term care nursing facilities that makes it difficult to vet prospective licensees of these types of facilities, under the existing requirements. Specifically, the Department has seen a shift in ownership from non-profit entities to for-profit entities. It has been estimated that nationwide, approximately 70 percent of long-term care nursing facilities are owned by for-profit entities. Gupta, A., et. al. "Does Private Equity Investment in Healthcare Benefit Patients? Evidence from Nursing Homes." (February 2021). Retrieved from https://bfi.uchicago.edu/wp-content/uploads/2021/02/BFI_WP_2021-20.pdf (hereinafter Gupta study).

The ownership structure of for-profit entities has become increasingly complex as owners have sought to protect themselves from liability. Complex ownership structures make it difficult to determine exactly who owns the facility, who owns the real property that the facility occupies, and most importantly, who exactly is responsible for the care of residents in the facility. This makes it difficult for residents, their families, and even regulators to hold owners accountable for the health and safety of residents. Private equity firms, in particular, have recently become interested in owning long-term care nursing facilities. Private equity firms are known for conducting leveraged buyouts, in which an entity is purchased by borrowing the cash needed to make the purchase. In the case of long-term care nursing facilities, private equity owners will often sell the facility's real estate assets shortly after the buyout to generate cash for their investors. This results in the need to pay rent. These rental payments, in addition to the debt incurred during the buyout, reduces the amount of cash available to provide for the care of residents. See Gupta study. This lack of cash can have dire consequences for residents in long-term care nursing facilities, as the facility is forced to cut costs, often by reducing staff. In some cases, the facility may end up closing due to its failure to meet its debt obligations, leaving residents and their families scrambling to find care elsewhere. A facility closure also negatively impacts employees who are laid off and forced to find other employment.

The Commonwealth and the Department experienced firsthand the detrimental impact a business failure can have on residents of a long-term care nursing facility with the failure of Skyline Healthcare. Strickler, L., et al. (July 2019). "A nursing home grows too fast and collapses, and elderly and disabled residents pay the price." Retrieved from <https://www.nbcnews.com/health/aging/nursing-home-chain-grows-too-fast-collapses-elderly-disabled-residents-n1025381> Here, in the Commonwealth, the Department was forced to install temporary management at nine facilities when it became clear that Skyline could no longer fiscally operate the facilities. Marselas, K. (May 2018). "Skyline's implosion continues with Pennsylvania takeover." Retrieved from <https://www.mcknights.com/news/skylines-implosion-continues-with-pennsylvania-takeover/>.

As a result, the Department has spent the past several years investigating the best way to evaluate prospective licensees of long-term care nursing facilities to protect the health and safety of residents and to prevent such a recurrence. The Department has determined that the best way to accomplish this is through the application for licensure process. The application process provides the Department with the opportunity to gather information into the background of a prospective licensee. Having as much information as possible regarding the background of a prospective licensee will aid the Department in vetting prospective licensees to determine whether they are a responsible person under the HCFA. The Department is requiring, among other things, information pertaining to a prospective licensee's financial stability, regulatory history in other jurisdictions, and prospective plans for the management of the facility. The Department is also adding a provision requiring prospective licensees to provide notice of

an application for new license to the Office of the State Long-Term Care Ombudsman and notice of an application for change in ownership to residents and their resident representatives, employees of the facility, and the Office of the State Long-Term Care Ombudsman, and providing for a 10-day public comment period to permit individuals to comment on the application for licensure. This type of information, which is not currently required under existing Federal or State law, will provide insight into a prospective licensee's ability to operate a long-term care nursing facility. This insight is vital in determining whether a prospective licensee can provide the care necessary for residents in a long-term care nursing facility and ensure their health and safety.

The Department is also requiring in § 201.14(j) (relating to responsibility of licensee) long-term care nursing facilities to conduct facility assessments that meet the requirements of 42 CFR 483.70(e), as necessary, but at least quarterly. Currently, under the Federal requirements for long-term care nursing facilities, a facility must conduct and document a facility-wide assessment to determine the resources necessary to care for its residents competently during both day-to-day operations and emergencies. The facility must review and update the assessment, as necessary, and at least annually. The Department has determined that quarterly assessments provide a more accurate mechanism through which a facility can determine the resources, particularly staffing levels, needed to properly care for residents. Throughout the year, a facility may experience changes in resident population, resident conditions and staff levels and competencies. Updating the facility assessment on at least a quarterly basis will allow a facility to properly assess the needs of residents and ensure that residents are receiving the most appropriate care and services.

The Department is also expanding § 201.22(b) (relating to prevention, control and surveillance of tuberculosis (TB)) to add "screening, testing and surveillance for TB" to clarify that this section applies to the screening, testing and surveillance of TB as well as the treatment and management of TB. The Federal requirements for long-term care nursing facilities do not specifically address TB. The Department has determined that it is important to keep this subsection to clarify that facilities must follow the Centers for Disease Control and Prevention (CDC) guidelines related to TB screening, testing and surveillance. The CDC provides the most updated guidance for facilities to follow regarding TB.

The Department is deferring to the Federal requirements in the areas of infection prevention and control, and fire protection and safety and emergency preparedness. The Federal requirements for infection prevention and control are located at 42 CFR 483.80 (relating to infection control). The Federal requirements for fire protection and safety and emergency preparedness are located at 42 CFR 483.90 (relating to physical environment) and 483.73 (relating to emergency preparedness). The Department is deleting §§ 209.1 (relating to fire department service), 209.7 (relating to disaster preparedness), and 209.8 (relating to fire drills) as these requirements are outdated and to eliminate any duplication between State and Federal requirements for long-term care nursing facilities.

(12) How does this regulation compare with those of the other states? How will this affect Pennsylvania's ability to compete with other states?

Other states require the submission of financial information and compliance history. As provided below, the requirements under this final-form are similar to the requirements in Ohio, Florida and Massachusetts. The Department reviewed regulations for the states surrounding Pennsylvania (Delaware, Maryland, Ohio and West Virginia), as well as regulations in Florida and Massachusetts. The Department did not compare regulations from New York and New Jersey, as those states require a Certificate of Need for licensure, whereas Pennsylvania and other surrounding states do not.

Delaware, Maryland, Ohio, Florida, and Massachusetts all require applicants to provide some type of financial information and history of ownership or compliance, although the degree to which this information is required varies. West Virginia does not specifically state the type of information that is required for the application for licensure. West Virginia also does not permit the transfer or assignment of a license. W. Va. Code R. § 64-13-3.

Delaware requires, in addition to the application, evidence that establishes the applicant's ability to comply with minimum standards of medical care or nursing care, financial capability, and any other applicable State and Federal laws and regulations. The applicant must complete a sworn affidavit of satisfactory compliance history and provide financial information for the past 5 years. Delaware does not permit assignment or transfer of a long-term care nursing facility. 16 Del. C. § 1104. Maryland requires applicants to provide information regarding past or current operation of a long-term care nursing facility, information regarding their ability to comply with Federal and State laws and regulations, and information regarding their financial and administrative ability to maintain a long-term care nursing facility, including submission of an audited financial statement. Md. Code Regs. 10.07.02.04.

Ohio requires prospective owners of new facilities to disclose names, addresses and telephone numbers of certain individuals, and to provide a statement of financial solvency. Ohio Admin. Code 3701-17-03. Under Ohio statute, before a facility may be assigned or transferred to another person, the prospective owner must provide documentation to demonstrate the person has all of the following: (1) financial resources to cover any reasonably anticipated revenue shortfall for at least twelve months; (2) at least 5 years' experience as an operator, manager or administrator of a long-term care nursing facility; (3) plans for quality assurance and risk management for the facility; and (4) general and professional liability insurance coverage of at least one million dollars per occurrence and three million dollars aggregate. Ohio Rev. Code § 3721.026. Florida also requires proof of financial ability to operate. Fla. Admin. Code r. 59A-35.062. Massachusetts is the most comprehensive of the states that the Department researched. In Massachusetts, prospective owners are subject to an evaluation process that considers factors such as financial stability and compliance history. Unlike the other states described above, in Massachusetts, prospective owners are also subject to a public notice requirement, a public comment period, and where requested, a hearing. 105 CMR 153.007 and 153.022.

Compared to certain surrounding states, the Department's amendments to the application process may be perceived as being more stringent. In addition, similar to Massachusetts and in response to public comments, the Department is also adding on final-form, a public notice and comment requirement. These financial reporting and public notice amendments are necessary to ensure that prospective owners are properly vetted to safeguard the health and safety of residents in long-term care nursing facilities.

The deletion of §§ 209.1, 209.7 and 209.8 to align with Federal requirements for long-term care nursing facilities will not impact Pennsylvania's ability to compete with other states. All long-term care nursing facilities that participate in the Federal Medicare or Medicaid programs are required to comply with the Federal standards and certification requirements for long-term care nursing facilities, regardless of where the facilities are located. Only three of the long-term care nursing facilities licensed by the Department do not participate in either the Medicare or Medical Assistance (MA) programs. As noted in Rulemaking 1, the Department reviewed the regulations of surrounding states to determine which states have adopted the Federal requirements as State licensing requirements. Of the states surrounding Pennsylvania, Delaware has expressly adopted the Federal requirements at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities). 16 Del. Admin. Code § 3201-1.21. New York

has not expressly adopted the Federal requirements but has a general provision in its regulations requiring that long-term care facilities comply with all pertinent Federal regulations. N.Y. Comp. Codes R. & Regs. tit. 10 § 415.1(4). Ohio, New Jersey, West Virginia, and Virginia have not expressly adopted the Federal requirements.

It does not appear that any of the above states require a facility assessment on a quarterly basis, as required by the Department in § 201.14(j). However, the Department believes that any impact on Pennsylvania's ability to compete based on this additional requirement will be minimal, as explained further in question 19.

(13) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

This final-form rulemaking will not affect the regulations of any other state agency. As provided above, the Department is currently updating the various regulatory chapters relating to long-term care facilities. This final-form rulemaking is the third of four rulemaking packages that amend the 6 chapters of Subpart C (relating to long-term care facilities) of 28 Pa. Code Part IV.

This final-form rulemaking amends sections related to applications for ownership, management and changes of ownership, and health and safety. The other three nursing facility regulatory packages are as follows:

Rulemaking 1 – *General Applicability and Definitions*

Rulemaking 2 – *General Operation and Physical Requirements*

Rulemaking 4 – *Qualifications, Training, Job Duties, Recordkeeping, Program Standards, and Resident Rights and Services*

(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. ("Small business" is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)

The Department's outreach has included various representatives from industry stakeholders and consumer advocacy groups, including small businesses and those groups representing them. As analyzed in further detail below, at least 91% of nursing facilities in the Commonwealth meet the definition of a small business due to \$30 million or less in annual receipts.

The Department began the process of updating the current long-term care nursing facilities regulations in late 2017. The Department sought review, assistance and advice from members of a long-term care work group (LTC Work Group) consisting of relevant stakeholders. The members of the LTC Work Group were drawn from a diverse background and included representatives from urban and rural long-term care facilities and various stakeholder organizations and consumer groups that work in the area of resident care and delivery of services. The LTC Work Group members consisted of representatives from the following organizations: American Institute of Financial Gerontology; Baker Tilly Virchow

Krause, LLP; Berks Heim and Rehabilitation; Fulton County Medical Center; Garden Spot Community; HCR ManorCare; Inglis House; Landis Communities; Leading Age; Legg Consulting Services; LIFE Pittsburgh; Luzerne County Community College; The Meadows at Blue Ridge; Mennonite Home, Lutheran Senior Life Passavant Community; PA Coalition of Affiliated Healthcare and Living Communities; Pennsylvania Home Care Association; University of Pittsburgh; and Valley View Nursing Home.

The members of the LTC Work Group met regularly during 2018 with the LTC Work Group's primary focus being the simplification and modernization of the existing long-term care regulations. After these discussions were complete, the Department reviewed the recommendations of the LTC Work Group and consulted with other potentially impacted agencies in 2019 and 2020. In 2020, 2021 and 2022, the Department continued its efforts to draft amendments to the long-term care nursing facility regulations while also handling the day-to-day challenges of protecting the residents of those facilities, who were being hit the hardest by the COVID-19 pandemic.

In 2019 and 2020, the Department consulted with the Department of Aging, Department of Human Services (DHS) and Department of Military and Veterans Affairs (DMVA), who also participated in the above LTC Work Group discussions. The Department presented the proposed regulations to the Health Policy Board on October 29, 2020.

In addition to considering comments on the four proposed regulatory packages during and outside of the four public comment periods, the Department also met with stakeholders on three occasions following the receipt of public and IRRC comments to discuss their concerns and to gain additional insight into comments that were received.

The first of these meetings occurred on December 15, 2021. Representatives from AARP, Alzheimer's Association – Delaware Valley and Greater Pennsylvania Chapters, Center for Advocacy for the Rights & Interests of the Elderly (CARIE), Community Legal Services, LeadingAge, Pennsylvania Health Care Association (PHCA), Pennsylvania Coalition of Affiliated Healthcare & Living Communities (PACAH), and SEIU Healthcare Pennsylvania attended that meeting.

The second meeting, for proposed Rulemaking 3, occurred on June 8, 2022. Representatives from AARP, Alzheimer's Association, CARIE, Community Legal Services, LeadingAge, PHCA, Pennsylvania Health Law Project (PHLP), and SEIU attended that meeting. The Department explicitly stressed to stakeholders during this June 8, 2022, meeting that it would be considering comments on all proposed rulemakings, and that it would welcome any additional comments or feedback that stakeholders might have after the meeting regarding proposed amendments to the regulations. The Department also indicated in a press release on June 3, 2022, that it would be considering comments on all four proposed rulemakings before submitting final-form regulations.

The Department held a third stakeholder meeting in August 2022 after the public and IRRC comment periods ended for proposed Rulemaking 4. The Department presented the final-form regulations to the Health Policy Board on August 10, 2022, and met with stakeholders one last time on August 17, 2022, to present the final-form regulations for final discussion and feedback. At this meeting, the Department presented stakeholders with an overview of the amendments that were made from proposed to final-form in response to their comments, on all four rulemakings, and provided them with an opportunity to comment and provide feedback on the final-form regulations. Present at that meeting were representatives from the Alzheimer's Association, CARIE, Community Legal Services, County Commissioners Association (CCAP), Disability Rights, LeadingAge, PHCA, PHFC, and SEIU.

In addition to this public outreach, the Senate Health and Human Services and Aging and Youth Committees held a joint legislative hearing regarding proposed Rulemaking 1 on September 15, 2021. The Department participated in the hearing and provided testimony and a commitment to continue working with stakeholders to address workforce challenges in the long-term care industry. The Department maintains this commitment and will continue to engage with stakeholders to provide guidance and technical assistance as the regulations are implemented and commits to continued engagement with stakeholders and other agencies to support ongoing workforce development in the long-term care industry.

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

Long-Term Care Nursing Facilities

The final-form rulemaking will affect the 682 long-term care nursing facilities licensed by the Department since these facilities will have to comply with the rulemaking. These facilities provide health services to approximately 72,000 residents. This total includes 19 county-owned and operated facilities, 6 veterans' homes that are operated by DMVA, 654 privately-owned facilities that participate in the Medicare and/or MA Programs, and 3 private-pay facilities that do not participate in either Medicare or MA.

The 19 county-owned long-term care nursing facilities licensed by the Department account for approximately 7.5% (6,524 beds) of licensed nursing facility beds across the Commonwealth. Allegheny County owns four of the nursing homes; the remaining homes are in the following 15 counties: Berks, Bradford, Bucks, Chester, Clinton, Crawford, Delaware, Erie, Indiana, Lehigh, Monroe, Northampton, Philadelphia, Warren and Westmoreland.

All 19 county-owned long-term care nursing facilities, as well as the 6 DMVA-operated facilities, participate in the Medicare or MA program and thus, are already required to comply with the Federal health and safety standards. Similarly, the 654 privately-owned facilities that participate in the Medicare or MA Programs are already required to comply with the incorporated Federal health and safety standards.

The three private-pay facilities have a combined capacity of 102 licensed beds of the approximate 72,000 residents. Further, these facilities had a reported, combined census reported of 79 residents for the Department's 2020-2021 annual report. Department of Health. (2021). Nursing Home Reports.

Retrieved from:

<https://www.health.pa.gov/topics/HealthStatistics/HealthFacilities/NursingHomeReports/Pages/nursing-home-reports.aspx>. These facilities are presently required to comply with the Federal requirements, as they existed on October 1, 1998, except for specified provisions relating to resident rights, admission, transfer and discharge, resident assessment, nursing, physician and dental services, physical environment and administration.

The existing regulations of the Department already incorporate many of the Federal health and safety requirements. Further, the incorporation of additional requirements impacts only those long-term care nursing facilities that do not participate in Medicare or MA. There are currently 3 private-pay long-term care nursing facilities that do not participate in either Medicare or MA. The regulated community will benefit from the efficiency of the consistent adoption and application of the Federal requirements for health and safety at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities).

The requirement to complete a facility assessment on at least a quarterly basis will affect all facilities that are currently not completing assessments at that level of frequency. Currently, facilities that participate in Medicare or MA are required to complete a facility assessment at least annually under 42 CFR 483.70(e); however, practice varies regarding frequency. The three private-pay facilities, who are operating under the 1998 Federal standards are not required to comply with 42 CFR 483.70(e) currently. Because facilities are already required to care for their residents, determine and plan for staffing, resources and operate their facilities, the conducting and documenting of a facility assessment is a standard business practice with a nominal fiscal impact due to the increase in required frequency. Quarterly facility assessments are used to determine what resources are needed to care for residents during both day-to-day operations and emergencies. Further, the assessments provide a timely indication of any systemic problems at a facility and assist with identifying areas for improvement.

Facilities will incur a nominal cost related to the submission of the annual financial report with applications and the renewal of the application for licensure under §§ 201.12 and 201.13c (relating to application for license of a new facility or change in ownership; license renewal). This will initially be a new requirement for all facilities effective October 31, 2023, followed by an annual update. Facilities should already have, in their possession, the documents required for the submission of the annual financial report, as these items are already produced in the regular course of business. However, facilities may incur a nominal cost for copying these documents for submission to the Department.

Prospective licensees will incur nominal costs related to the submission of additional documents with the application for licensure in § 201.12 (relating to application for license of a new facility or change in ownership). Prospective licensees should already have, in their possession, the financial documents and other information listed in § 201.12, as many of these documents are already produced in the regular course of business. However, prospective licensees may incur nominal costs for copying these documents for submission to the Department. Prospective licensees will need to spend time compiling this information for submission to the Department, as well. The Department anticipates that a prospective licensee will need to spend approximately an hour compiling this information for submission. Prospective licensees will need to expend time developing other items required under § 201.12, such as a staffing plan and an emergency preparedness plan. The Department anticipates that a prospective licensee may need to spend approximately 2 to 4 hours developing these items. Prospective licensees will also incur nominal costs, such as postage and the cost of paper and supplies, associated with providing the notice under § 201.12a (relating to notice and opportunity to comment) to the Office of the State Long-Term Care Ombudsman and residents, resident representatives, and employees, if applicable. The Department anticipates that a prospective licensee may need to expend anywhere from a few minutes to an hour, depending on the number of notices required under this section. Prospective licensees may incur additional costs if they choose to consult with an accountant or an attorney when completing these paperwork requirements.

Small Business Analysis

Under section 3 of the Regulatory Review Act, 71 P.S. § 745.3, a small business is “defined in accordance with the size standards described by the United States Small Business Administration’s Small Business Size Regulations under 13 CFR Ch. 1 Part 121 (relating to Small Business Size Regulations) or its successor regulation.” Under 13 CFR 121.101 (relating to what are SBA size standards), the Small Business Administration’s (SBA) “size standards determine whether a business entity is small.” Size standards are developed under the North America Industry Classification System (NAICS). The Department applied the NAICS standards to determine how many long-term care nursing

facilities, licensed by the Department, are small businesses. Based on these federal standards, the Department determined that a long-term care nursing facility is a small business if it has \$30 million or less in annual receipts.

Based on the analysis of the latest long-term care nursing facility cost reports from the Centers for Medicare & Medicaid Services (CMS), the Department determined that 623 facilities that participate in Medicare and/or MA have \$30 million or less in annual receipts. In making this determination, the Department applied current Federal Standards of Accounting to this data to determine each facility's annual receipts. The latest cost report data from CMS is 2018. Data.CMS.gov. Skilled Nursing Facility Cost Report. Retrieved from <https://data.cms.gov/provider-compliance/cost-report/skilled-nursing-facility-cost-report/data>. Although the data from CMS is from 2018, the Department expects a consistent number of facilities to meet the definition of a small business.

The Department also asked stakeholders during the meetings held in 2021 and 2022 for assistance in determining the impact to small businesses. The stakeholders were not able to provide the Department with specific information regarding how the Department's proposed regulations would impact small businesses. However, during the stakeholder meeting for Rulemakings 1 and 2, a stakeholder suggested that the Department search GuideStar, which provides financial information regarding nonprofit entities, to determine whether the three private-pay facilities are small businesses. The Department searched the GuideStar website at <https://www.guidestar.org/> for the three private-pay facilities that are licensed by the Department. Based on this data, one of the private-pay facilities, Friends Home in Kennett/Linden Hall, meets the definition of a small business under NAICS standards. Another private-pay facility, Foulkeways at Gwynedd does not meet the definition of a small business under NAICS standards because its gross receipts exceed \$30 million. Data for the third private-pay facility, Dallastown Nursing Center, is not available on GuideStar, but for the purposes of this analysis, the Department assumes that Dallastown, similar to other nursing facilities, is a small business.

In sum, at least 91% of nursing facilities meet the definition of a small business. Consistent with the HCFA and function of licensure, the purpose of these regulatory amendments is to ensure the health, safety, and welfare of all residents of long-term care nursing facilities in this Commonwealth by providing the minimum health and safety standards. Given that most nursing facilities are a small business and the need for surveying for the health and safety of residents, the Department did not establish differing criteria for nursing facilities that are small businesses compared to the minority of facilities that are not small businesses. Further, in determining the minimum health and safety requirements, the Department considered the myriad of received comments, feedback from meetings and stakeholder groups and attempted to balance the interests between consumers and the stakeholder industry. The Department's responsibility to ensure that residents receive safe, quality care applies to all residents of long-term care nursing facilities in this Commonwealth, and it is critical that all residents of long-term care nursing facilities receive the same level of high-quality care, regardless of whether the facility they reside in is a small business.

Residents of Long-Term Care Nursing Facilities

Approximately 72,000 individuals that reside in the 682 long-term care nursing facilities licensed by the Department will be affected by the amendments. Residents will be positively impacted by the increased frequency in facility assessments. As provided previously, quarterly assessments are used to determine what resources are needed to care for residents during both day-to-day operations and emergencies. Further, these assessments provide a timely indication of any systemic problems at a facility and assist with identifying areas for improvement. Specifically, analyzing the resident population every quarter provides a snapshot as to the overall conditions of the residents at that time, including the most common

diseases, conditions, and diagnoses during that time period, and if the facility has the appropriate staff and/or equipment to take care of those residents, particularly if a trend is found among those residents.

Department

The Department licenses long-term care nursing facilities. The Department’s surveyors perform the function of surveying and inspecting long-term care nursing facilities for compliance with both Federal and State regulations. The Department does not expect there to be an increase in costs associated with its responsibility to survey long-term care nursing facilities as a result of this rulemaking. As noted in Rulemaking 1 – *General Applicability and Definitions*, it is anticipated that the adoption of the Federal requirements will create consistency in the licensing and survey process for long-term care nursing facilities because the same standards will now apply to all long-term care nursing facilities in the Commonwealth. This will result in a more streamlined licensing and inspection process for both the Department and long-term care nursing facilities operating in the Commonwealth.

However, the Department is anticipating a cost of \$600,000 to hire accountants to establish a financial unit to review and manage the new financial submissions from facilities. This estimate includes an estimated \$590,312 for salaries and benefits and initial operating costs of \$9,250 for equipment and office space. The delayed implementation date will allow prospective licensees and licensees time to adjust to this new requirement and also provide time for the Department to establish this financial unit.

The Department also estimates that there will be a cost to update licenses to add the additional information under § 201.13 (relating to issuance of license for new facility or change in ownership) and to update the computer system for the creation of internal reporting or review of new information. It is estimated that the Department will need to expend approximately \$55,000 for these updates, which includes the cost for a vendor assessment. The delayed implementation date will allow the Department time to complete the vendor assessment and make the necessary updates.

Department of Human Services

Although the provisions of this final-form rulemaking, which relate to incorporation of federal health and safety standards and the updating of licensure, management and change in ownership provisions, will not have a cost impact to the Department of Human Services, a substantial increase in funding for nursing facilities, including new nursing facility funding and increased MA payments beginning January 2023, was enacted under Act 2022-54 and appropriated under the General Appropriations Act of 2022 (Act 2022-1A).

Department of Military and Veterans Affairs

This final-form rulemaking will not have a cost impact to DMVA since its facilities already participate in the Medicare and MA Programs. Although there will be additional paperwork requirements associated with quarterly facility assessments, DMVA has indicated to the Department that it considers conducting a quarterly facility assessment to be a standard business practice, and the increase in required frequency will have a nominal fiscal impact that can be absorbed by the facilities’ current workforce.

(16) List the persons, groups or entities, including small businesses, that will be required to comply with the regulation. Approximate the number that will be required to comply.

All 682 licensed long-term care nursing facilities in the Commonwealth will be required to comply with the health and safety standards of this final-form rulemaking. At least 91% of nursing facilities meet the definition of a small business. These facilities provide care to approximately 72,000 residents.

As provided above, pursuant to section 3 of the Regulatory Review Act (71 P.S. § 745.3), the Department applied the NAICS standards to determine how many long-term care nursing facilities licensed by the Department are small businesses. Based on the latest cost report from CMS, the Department determined that 623 facilities that participate in the Medicare and/or MA Programs meet the definition of small business since they have \$30 million or less in annual receipts. The latest cost report data from CMS is available at <https://data.cms.gov/provider-compliance/cost-report/skilled-nursing-facility-cost-report/data>.

Based on GuideStar, which provides financial information regarding nonprofit entities, one of the private-pay facilities, Friends Home in Kennett/Linden Hall meets the definition of a small business under NAICS standards. Another private-pay facility, Foulkeways at Gwynedd does not meet the definition of a small business under NAICS standards because its gross receipts exceed \$30 million. Data for the third private-pay facility, Dallastown Nursing Center, is not available on GuideStar, but for the purposes of this analysis, the Department assumes that Dallastown, similar to other nursing facilities, is a small business. <https://www.guidestar.org/>

(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.

Long-Term Care Nursing Facilities

This final-form rulemaking applies to all 682 licensed long-term care nursing facilities in the Commonwealth. At least 91% of nursing facilities meet the definition of a small business. These facilities provide health services to approximately 72,000 residents. The existing regulations of the Department already incorporate many of the Federal requirements and the expansion to incorporate the remaining Federal requirements at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities) will impact the 3 long-term care nursing facilities that do not participate in either the Medicare or MA Program. The benefit of this final-form rulemaking is consistent standards for licensure to ensure the health, safety, and welfare of all residents of long-term care nursing facilities in this Commonwealth.

The requirement to complete a facility assessment on at least a quarterly basis will affect all facilities that are currently not completing assessments at that level of frequency. Currently, facilities that participate in Medicare or MA are required to complete a facility assessment at least annually under 42 CFR 483.70(e); however, practice varies regarding frequency. The three private-pay facilities, who are operating under the 1998 Federal standards are not required to comply with 42 CFR 483.70(e) currently. Because facilities are already required to care for their residents, determine and plan for staffing, resources and operate their facilities, the conducting and documenting of a facility assessment is a standard business practice with a nominal fiscal impact due to the increase in required frequency. Quarterly facility assessments are used to determine what resources are needed to care for residents during both day-to-day operations and emergencies. Further, the assessments provide a timely indication of any systemic problems at a facility and assist with identifying areas for improvement.

IRRC asked that the Department work with the regulated community to calculate and address the economic impact of additional quarterly assessments on facilities, particularly those that are small

businesses. Although the Department inquired regarding the economic impact during a June stakeholder meeting, no comments or responses were provided. As additional background, when facility assessments were first required through the Federal Department of Health and Human Services (DHHS), due to existing requirements for sufficient staffing for acuity needs, no fiscal impact or burden was anticipated. Specifically, DHHS provided:

“We are finalizing our requirement for facilities to conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. LTC facilities must already determine and plan for what staffing they will need, as well as the other resources that will be required to care for their residents and operate their facilities. Thus, we believe that conducting and documenting a facility assessment is a standard business practice and do not include a burden for this requirement in the impact analysis.”

81 FR 68688, 68844 (October 4, 2016)

In working with DMVA, who operates 6 long-term care nursing facilities, DMVA indicated that the cost of conducting a facility assessment is insignificant, as it just involves compiling information. DMVA does not anticipate an increase in costs or labor to meet the increased frequency of this currently utilized assessment. DMVA currently has quality assurance staff perform this function.

Facilities will incur a nominal cost related to the submission of the annual financial report with the renewal of the application for licensure under § 201.13c (relating to license renewal). This will initially be a new requirement for all facilities effective October 31, 2023, followed by an annual update. Facilities should already have, in their possession, the documents required for the submission of the annual financial report, as these items are already produced in the regular course of business. However, facilities may incur a nominal cost for copying these documents for submission to the Department.

In response to stakeholder and IRRC comments, the Department has delayed implementation of these requirements to ensure the regulated community has sufficient time to prepare for and implement these new requirements and the Department is prepared to receive and analyze the information submitted. The delayed implementation will benefit all facilities, including the 91% of facilities that are small businesses.

Prospective licensees

Prospective licensees will incur nominal costs related to the submission of additional documents with the application for licensure in § 201.12 (relating to application for license of a new facility or change in ownership). Prospective licensees should already have, in their possession, the financial documents and other information listed in § 201.12, as many of these documents are already produced in the regular course of business. However, prospective licensees may incur nominal costs for copying these documents for submission to the Department. Prospective licensees will need to spend time compiling this information for submission to the Department, as well. The Department anticipates that a prospective licensee will need to spend approximately an hour compiling this information for submission. Prospective licensees will need to expend time developing other items required under § 201.12, such as a staffing plan and an emergency preparedness plan. The Department anticipates that a prospective licensee may need to spend approximately two to four hours developing these items. Prospective licensees will also incur nominal costs, such as postage and the cost of paper and supplies, associated with providing the notice under § 201.12a (relating to notice and opportunity to comment) to

the Office of the State Long-Term Care Ombudsman and residents, resident representatives, and employees, if applicable. The Department anticipates that a prospective licensee may need to expend anywhere from a few minutes to an hour, depending on the number of notices required under this section. Prospective licensees may incur additional costs if they choose to consult with an accountant or an attorney when completing these paperwork requirements.

Department of Human Services

Although the provisions of this final-form rulemaking, which relate to incorporation of federal health and safety standards and the updating of licensure, management and change in ownership provisions, will not have a cost impact to the Department of Human Services, a substantial increase in funding for nursing facilities, including new nursing facility funding and increased MA payments beginning January 2023, were enacted under Act 2022-54 and appropriated under the General Appropriations Act of 2022 (Act 2022-1A).

Department of Military and Veterans Affairs

This final-form rulemaking will not have a cost impact to DMVA since its facilities already participate in the Medicare and MA Programs. Although there will be additional paperwork requirements associated with quarterly facility assessments, DMVA has indicated to the Department that it considers conducting a quarterly facility assessment to be a standard business practice, and the increase in required frequency which will have a nominal fiscal impact.

Residents of Long-Term Care Nursing Facilities

This final-form rulemaking will have a social impact and benefit for the more than 72,000 residents in the 682 licensed long-term care nursing facilities. Residents will benefit from the adoption of the Federal requirements because the same standards will now be applied to all long-term care nursing facilities, regardless of whether those facilities participate in the Medicare or MA Programs. Specifically, residents, and their family members, will benefit from the peace of mind in knowing that the same standards of care are being applied regardless of whether the facility participates in a Federally-funded program or not. Residents, prospective residents, and their family members will also benefit from new and updated requirements related to the application for licensure process. These new and updated provisions will ensure that prospective licensees are properly vetted before assuming ownership of a facility and will provide much needed transparency in the application for licensure process, which will also provide peace of mind and will enable residents and their family members to make informed decisions regarding where to go for their care.

(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.

Although there is anticipated to be a fiscal impact regarding incorporation of certain federal standards for the three facilities that do not participate in Medicare or MA Programs, the cost of these health and safety standards is outweighed by the health and safety benefits for nursing facility residents. The benefit of this final-form rulemaking is consistent standards for licensure to ensure the health, safety, and welfare of all residents of long-term care nursing facilities in this Commonwealth.

While there may be a nominal fiscal impact related to the requirement for a quarterly facility assessment, this cost is outweighed by the benefit of the assessment, which aids the facility in determining what resources are needed to care for residents, during both day-to-day operations and emergencies; providing a timely indication of any systemic problems in the facility; and assisting with identifying areas for improvement.

While there may be a nominal fiscal impact to current facility licensees and prospective licensees related to the additional paperwork requirements in § 201.12 and § 201.13c, this cost is outweighed by the benefit current and future residents, and their families, will receive from the stricter scrutiny and the transparency in ownership structures that these requirements will provide.

(19) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

The existing regulations of the Department already incorporate many of the Federal health and safety requirements. Further, the incorporation of additional requirements impacts only those long-term care nursing facilities that do not participate in Medicare or MA. There are currently 3 private-pay long-term care nursing facilities that do not participate in either Medicare or MA. The estimated cost impact for the expansion of the adoption of the Federal requirements is provided for in Rulemaking 1.

As noted in that rulemaking, based on the Department's experience with facilities' compliance with existing regulatory requirements, these facilities already comply with many of the Federal requirements. Additionally, requiring all long-term care nursing facilities to comply with the minimum Federal health and safety standards for long-term care facilities will increase health and safety standards, improve the survey process, create consistency and eliminate any confusion in the application of standards to long-term care nursing facilities, which will benefit all long-term care nursing facilities. Although there is anticipated to be a fiscal impact regarding incorporation of certain federal standards for the three facilities that do not participate in Medicare or MA Programs, the cost of these health and safety standards is outweighed by the health and safety benefits for nursing facility residents. The benefit of this final-form rulemaking is consistent standards for licensure to ensure the health, safety, and welfare of all residents of long-term care nursing facilities in this Commonwealth.

The requirement to complete a facility assessment on at least a quarterly basis will affect all facilities that are currently not completing assessments at that level of frequency. Currently, facilities that participate in Medicare or MA are required to complete a facility assessment at least annually under 42 CFR 483.70(e); however, practice varies regarding frequency. The three private-pay facilities, who are operating under the 1998 Federal standards are not required to comply with 42 CFR 483.70(e) currently. Because facilities are already required to care for their residents, determine and plan for staffing, resources and operate their facilities, the conducting and documenting of a facility assessment is a standard business practice with a nominal fiscal impact due to the increase in required frequency. Quarterly facility assessments are used to determine what resources are needed to care for residents during both day-to-day operations and emergencies. Further, the assessments provide a timely indication of any systemic problems at a facility and assist with identifying areas for improvement.

Facilities will incur a nominal cost related to the submission of the financial reporting with the submission of new applications and the renewal of the application for licensure. This will initially be a new requirement for all facilities, followed by an annual update. Facilities should already have, in their possession, the documents required for the submission of the annual financial report, as these items are already produced in the regular course of business. However, facilities may incur a nominal cost for copying these documents for submission to the Department. The effective date for these financial reporting requirements is October 31, 2023.

As provided above, the cost of these health and safety standards, and application for licensure requirements, is outweighed by the health and safety benefits for nursing facility residents. The benefit of this final-form rulemaking is consistent standards for licensure to ensure the health, safety, and welfare of all residents of long-term care nursing facilities in this Commonwealth.

(20) Provide a specific estimate of the costs and/or savings to the **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

There are currently 19 county-owned long-term care nursing facilities which account for approximately 7.5 percent (6,524 beds) of long-term care nursing beds across the Commonwealth. Allegheny County owns four of the nursing homes; the remaining homes are in the following 15 counties: Berks, Bradford, Bucks, Chester, Clinton, Crawford, Delaware, Erie, Indiana, Lehigh, Monroe, Northampton, Philadelphia, Warren, and Westmoreland.

All of the county-owned long-term care nursing facilities participate in either the Medicare or MA Programs and, thus, will not be impacted by the Department's incorporation of the Federal health and safety requirements.

The requirement to complete a facility assessment on at least a quarterly basis will impact county-owned facilities that are currently not completing assessments at that level of frequency. Currently, the county-owned facilities are required to complete a facility assessment at least annually under 42 CFR 483.70(e); however, practice varies regarding frequency. Because facilities are already required to care for their residents, determine and plan for staffing, resources and operate their facilities, the conducting and documenting of a facility assessment is a standard business practice with a nominal fiscal impact due to the increase in required frequency. Quarterly facility assessments are used to determine what resources are needed to care for residents during both day-to-day operations and emergencies. Further, the assessments provide a timely indication of any systemic problems at a facility and assist with identifying areas for improvement.

(21) Provide a specific estimate of the costs and/or savings to the **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

Department

The Department licenses long-term care nursing facilities. The Department's surveyors perform the function of surveying and inspecting long-term care nursing facilities for compliance with both Federal and State regulations. The Department does not expect there to be any increase in costs associated with

its responsibility to license and survey long-term care nursing facilities under this final-form rulemaking. As noted in Rulemaking 1, it is anticipated that the adoption of the Federal requirements will create consistency in the licensing and survey process for long-term care nursing facilities because the same standards will now apply to all long-term care nursing facilities in the Commonwealth. This will result in a more streamlined licensing and inspection process for both the Department and long-term care nursing facilities operating in the Commonwealth.

However, the Department is anticipating a cost of \$600,000 to hire accountants to establish a financial unit to review and manage the new financial submissions from facilities. This estimate includes an estimated \$590,312 for salaries and benefits and initial operating costs of \$9,250 for equipment and office space.

The Department also estimates that there will be a cost to update licenses to add the additional information under § 201.13 (relating to issuance of license for new facility or change in ownership) and to update the computer system for the creation of internal reporting or review of new information. It is estimated that the Department will need to expend approximately \$55,000 for these updates, which includes the cost for a vendor assessment.

Department of Human Services

Although the provisions of this final-form rulemaking, which relate to incorporation of federal health and safety standards and the updating of licensure, management and change in ownership provisions, will not have a cost impact to the Department of Human Services, a substantial increase in funding for nursing facilities, including new nursing facility funding and increased MA payments beginning January 2023, was enacted under Act 2022-54 and appropriated under the General Appropriations Act of 2022 (Act 2022-1A).

Department of Military and Veterans Affairs

This final-form rulemaking will not have a cost impact to DMVA since its facilities already participate in the Medicare and MA Programs. Although there will be additional paperwork requirements associated with quarterly facility assessments, DMVA has indicated to the Department that it considers conducting a quarterly facility assessment to be a standard business practice, and the increase in required frequency which will have a nominal fiscal impact.

(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

Under this final-form rulemaking, there are additional reporting and paperwork requirements related to the quarterly facility assessment and also the increased application and renewal process, including the submittal of financial information. The Department is not proposing a specific format for the submission of this paperwork. The new financial reporting requirements will be effective October 31, 2023.

(22a) Are forms required for implementation of the regulation?

There are no new forms required for implementation of this final-form rulemaking. The form required for the application for licensure in § 201.12 and renewal of a license in § 201.13c is one and the same and will not change under this rulemaking. A copy of this form is attached as Exhibit A.

(22b) If forms are required for implementation of the regulation, **attach copies of the forms here**. If your agency uses electronic forms, provide links to each form or a detailed description of the information required to be reported. **Failure to attach forms, provide links, or provide a detailed description of the information to be reported will constitute a faulty delivery of the regulation.**

There are no new forms required for implementation of this final-form rulemaking. The form required for the application for licensure in § 201.12 and renewal of a license in § 201.13c is one and the same and will not change under this rulemaking. A copy of this form is attached as Exhibit A.

(23) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY 2022-2023	FY +1 2023-2024	FY +2 2024-2025	FY +3 2025-2026	FY +4 2026-2027	FY +5 2027-2028
SAVINGS:	\$	\$	\$	\$	\$	\$
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Savings	0	0	0	0	0	0
COSTS:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0 ¹	654,562 ²	619,828	650,819	683,360	717,528

¹ The regulation will become effective on July 1, 2023, §§ 201.12, 201.12a, 201.12b, 201.13c(b) and (c) taking effect October 31, 2022. Therefore, there will be no costs for the regulation in the current fiscal year.

² As described in question 21, this number represents the following: an estimated \$590,312 in salary and benefits for employees of the new, proposed financial unit; a one-time estimate of \$9,250 in initial operating costs for the proposed financial unit; and a one-time estimate of \$55,000 to make these updates; this cost includes a vendor assessment. The Department subtracted the initial operating costs and one-time estimate to calculate costs for fiscal years 2024-2025, 2025-2026, 2026-2027 and 2027-28. The Department is estimating a 5% increase in salaries and benefits for the financial unit employees for these fiscal years.

Total Costs	0	654,562	619,828	650,819	683,360	717,528
REVENUE LOSSES:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Revenue Losses	0	0	0	0	0	0

(23a) Provide the past three-year expenditure history for programs affected by the regulation.

Program	FY -3 2019-2020	FY -2 2020-2021	FY -1 2021-2022	Current FY 2022-2023
DOH Quality Assurance	22,513,000	23,093,000	24,393,000	25,349,000
MA – Long-Term Care	470,244,000	208,841,000	121,346,000	165,981,000
MA – Community Health Choices	2,328,939,000	3,165,550,000	4,251,550,000	5,061,602,000
DMVA (actual expenditures)	80,108,213	80,386,733	77,671,425	82,903,586

(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:

- (a) An identification and estimate of the number of small businesses subject to the regulation.

This final-form rulemaking applies to all 682 licensed long-term care nursing facilities in the Commonwealth. At least 91% of nursing facilities meet the definition of a small business. These facilities provide health services to approximately 72,000 residents. This total includes 19 county-owned and operated facilities, 6 veterans' homes that are operated by DMVA, 654 privately-owned facilities that participate in Medicare and/or MA, and three private-pay facilities that do not participate in either Medicare or MA.

Under section 3 of the Regulatory Review Act, 71 P.S. § 745.3, a small business is "defined in accordance with the size standards described by the United States Small Business Administration's Small Business Size Regulations under 13 CFR Ch. 1 Part 121 (relating to Small Business Size Regulations) or its successor regulation." Under 13 CFR 121.101 (relating to what are SBA size standards), the Small Business Administration's (SBA) "size standards determine whether a business entity is small." Size standards are developed under the North America Industry Classification System (NAICS). The Department applied the NAICS standards to determine how many long-term care nursing facilities, licensed by the Department, are small businesses. Based on these federal standards, the Department determined that a long-term care nursing facility is a small business if it has \$30 million or less in annual receipts.

Based on the analysis of the latest long-term care nursing facility cost reports from the Centers for Medicare & Medicaid Services (CMS), the Department determined that 623 facilities that participate in Medicare and/or MA have \$30 million or less in annual receipts. In making this determination, the Department applied current Federal Standards of Accounting to this data to determine each facility's annual receipts. The latest cost report data from CMS is 2018. Data.CMS.gov. Skilled Nursing Facility Cost Report. Retrieved from <https://data.cms.gov/provider-compliance/cost-report/skilled-nursing-facility-cost-report/data>. Although the data from CMS is from 2018, the Department expects a consistent number of facilities to meet the definition of a small business.

The Department also asked stakeholders during the meetings held in 2021 and 2022 for assistance in determining the impact to small businesses. The stakeholders were not able to provide the Department with specific information regarding how the Department's proposed regulations would impact small businesses. However, during the stakeholder meeting for Rulemakings 1 and 2, a stakeholder suggested that the Department search GuideStar, which provides financial information regarding nonprofit entities, to determine whether the three private-pay facilities are small businesses. The Department searched the GuideStar website at <https://www.guidestar.org/> for the three private-pay facilities that are licensed by the Department.

Based on this data, one of the private-pay facilities, Friends Home in Kennett/Linden Hall meets the definition of a small business under NAICS standards. Another private-pay facility, Foulkeways at Gwynedd does not meet the definition of a small business under NAICS standards because its gross receipts exceed \$30 million. Data for the third private-pay facility, Dallastown Nursing Center, is not available on GuideStar, but for the purposes of this analysis, the Department assumes that Dallastown, similar to other nursing facilities, is a small business.

As provided above, at least 91% of nursing facilities meet the definition of a small business. Consistent with the HCFA and function of licensure, the purpose of these regulatory amendments is to ensure the health, safety, and welfare of all residents of long-term care nursing facilities in this Commonwealth by providing the minimum health and safety standards. Given that most facilities are a small business and the need for surveying for the health and safety of residents, the Department did not establish differing criteria for nursing facilities that are small business compared to the minority of facilities that are not small businesses. Further, in determining the minimum health and safety requirements, the department considered the myriad of received comments, feedback from meetings and stakeholder groups and attempted to balance the interests between consumers and the stakeholder industry. The Department's responsibility to ensure that residents receive safe, quality care applies to all residents of long-term care nursing facilities in this Commonwealth, and it is critical that all residents of long-term care nursing facilities receive the same level of high-quality care, regardless of whether the facility they reside in is a small business under NAICS standards.

- (b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.

As stated above, there are additional reporting and paperwork requirements related to the quarterly facility assessment and also the increased application process, including the submittal of financial information. The Department is not proposing a specific format for the submission of this paperwork.

Given the current business practice for the quarterly assessments and the accessibility of the needed financial reporting documents, the Department does not anticipate a financial burden in submitting these reporting and paperwork requirements.

(c) A statement of probable effect on impacted small businesses.

See Question 15. Small businesses will be affected by these regulations in the same manner as other facilities that are not small businesses. Further, the Department anticipates that only two of the three private-pay facilities meet the definition of a small business, with gross receipts under \$30 million.

(d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

The Department did not identify any less costly alternative that would be consistent with public health and safety. However, the department is providing a delayed implementation date of October 31, 2023 for the financial reporting requirements.

(25) List any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, the elderly, small businesses, and farmers.

No special provisions have been developed as this final-form rulemaking applies to long-term care nursing facilities. Specifically, the regulations apply to all 682 long-term care nursing facilities in the Commonwealth, which serve approximately 72,000 nursing facility residents.

In response to stakeholder and IRRC comments, the Department is extending the effective date of has delayed implementation of these requirements to ensure the regulated community has sufficient time to prepare for and implement these new requirements and the Department is prepared to receive and analyze the information submitted. The delayed implementation will benefit all nursing facilities, including the 91% of facilities that are small businesses.

(26) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

The Department considered public comments related to the information that is required to be submitted with an application for licensure, as well as comments related to the requirements related to annual financial reports. There were various comments suggesting that the Department require a wide range of detailed financial information. The requirements included on final form represent the least burdensome alternatives that protect resident health and safety and are responsive to emerging concerns related to ownership of long-term care nursing facilities.

(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:

- a) The establishment of less stringent compliance or reporting requirements for small businesses;
- b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;

- c) The consolidation or simplification of compliance or reporting requirements for small businesses;
- d) The establishment of performance standards for small businesses to replace design or operational standards required in the regulation; and
- e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

(a) As provided above, the purpose of these amendments is to ensure the health, safety, and welfare of all residents of long-term care nursing facilities in this Commonwealth. Further, at least 91% of nursing facilities meet the definition of a small business with gross receipts under \$30 million. Given the need for minimum health and safety requirements, coupled with the overwhelming majority of facilities meeting the definition of a small business, the Department did not establish less stringent compliance or reporting requirements.

(b) This final-form rulemaking does not have any less stringent or alternative schedules or deadlines for small businesses, which as defined, include at least 91% of nursing facilities. In response to stakeholder and IRRC comments, the Department has delayed implementation of these requirements to ensure the regulated community has sufficient time to prepare for and implement these new requirements and the Department is prepared to receive and analyze the information submitted. The delayed implementation will benefit all nursing facilities, including the 91% of facilities that are small businesses.

(c) This final-form rulemaking does not have any consolidated or alternative reporting requirements for small businesses, which as defined, include at least 91% of nursing facilities.

(d) This final-form rulemaking does not have alternative design or operational standards for small businesses, which as defined, include at least 91% of nursing facilities.

(e) This final-form rulemaking does not have specific exemptions for small businesses since, as defined, this includes at least 91% of nursing facilities.

(28) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

The Department relied on data obtained from the following sources:

Penn State Harrisburg, Pennsylvania State Data Center. (July 2018). *Population Characteristics and Change: 2010 to 2017 (Research Brief)*. <https://pasdc.hbg.psu.edu/data/research-briefs/pa-population-estimates> (report compiled based on US census data).

Penn State Harrisburg, Pennsylvania State Data Center. (June 2022). *Population in Pennsylvania's Population by Age*. (Research Brief). Retrieved from https://pasdc.hbg.psu.edu/sdc/pasdc_files/researchbriefs/June_2022.pdf.

Administration for Community Living. (February 2020). How Much Care Will You Need? Retrieved from <https://acl.gov/ltc/basic-needs/how-much-care-will-you-need>.

Demographic Trends of COVID-19 Cases and Deaths in the US Reported to CDC. Retrieved from <https://covid.cdc.gov/covid-data-tracker/#demographics>.

The COVID Tracking Project. (March 2021). Long-Term-Care COVID Tracker. Retrieved from <https://covidtracking.com/nursing-homes-long-term-care-facilities>.

Kaiser Family Foundation. *Nursing Facilities, Staffing, Residents and Facility Deficiencies: 2009 through 2016*. (2018). <https://www.kff.org/medicaid/report/nursing-facilities-staffing-residents-and-facility-deficiencies-2009-through-2016> (last visited: November 25, 2020) (study of long-term care facilities conducted in 2018).

AARP Nursing Home COVID-19 Dashboard Fact Sheets. Retrieved from <https://www.aarp.org/ppi/issues/caregiving/info-2020/nursing-home-covid-states.html>.

The Adverse Effects of the COVID-19 Pandemic on Nursing Home Resident Well-Being.” *Journal of the American Medical Directors Association*, 22(5), 948-954.e2. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7980137/>.

“Front-line Nursing Home Staff Experiences During the COVID-19 Pandemic.” *Journal of the American Medical Directors Association*, 22(1), 199-203. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7685055/>.

Department of Health. (2021). *Nursing Home Reports*. Retrieved from: <https://www.health.pa.gov/topics/HealthStatistics/HealthFacilities/NursingHomeReports/Pages/nursing-home-reports.aspx>.

State Policies Related to Nursing Facility Staffing. Retrieved from: <https://www.macpac.gov/publication/state-policies-related-to-nursing-facility-staffing/>

Gross Receipt Information -GuideStar Website - <https://www.guidestar.org/>

Gupta, A., et al. “Does Private Equity Investment in Healthcare Benefit Patients? Evidence from Nursing Homes.” (February 2021). Retrieved from https://bfi.uchicago.edu/wp-content/uploads/2021/02/BFI_WP_2021-20.pdf

Strickler, L., et al. (July 2019). “A nursing home grows too fast and collapses, and elderly and disabled residents pay the price.” Retrieved from <https://www.nbcnews.com/health/aging/nursing-home-chain-grows-too-fast-collapses-elderly-disabled-residents-n1025381>

Marselas, K. (May 2018). “Skyline’s implosion continues with Pennsylvania takeover.” Retrieved from <https://www.mcknights.com/news/skylines-implosion-continues-with-pennsylvania-takeover/>

(29) Include a schedule for review of the regulation including:

A. The length of the public comment period:

B. The date or dates on which any public meetings or hearings will be held:

- The proposed regulations were presented to the Health Policy Board on October 29, 2020.
- On September 15, 2021, a public hearing was held before the Senate Aging & Youth Committee and the Senate Health & Human Services Committee, during which advocates provided feedback on proposed rulemaking 1.
- The Department held meetings on December 15, 2021, June 8, 2022, and August 3, 2022. The Department invited stakeholders and commentators to these meetings to discuss their comments on the proposed regulations.
- The final-form regulations were presented to the Health Policy Board on August 10, 2022.
- The Department held a meeting on August 17, 2022. At this meeting, the Department presented stakeholders with an overview of the amendments that were made from proposed to final-form in response to their comments, on all four rulemakings, and provided them with an additional opportunity to comment and provide feedback on the final-form regulations.

C. The expected date of delivery of the final-form regulation: September 2022

D. The expected effective date of the final-form regulation: July 1, 2023, except as follows:
Section 201.12a(a),(b) and (c)(1)-(3) will take effect February 1, 2023. Sections 201.12, 201.12a(c)(4) and (d), 201.12b, 201.13c(b) and (c) will take effect October 31, 2023.

E. The expected date by which compliance with the final-form regulation will be required: July 1, 2023, except as follows:
Section 201.12a(a),(b) and (c)(1)-(3) will take effect February 1, 2023. Sections 201.12, 201.12a(c)(4) and (d), 201.12b, 201.13c(b) and (c) will take effect October 31, 2023.

F. The expected date by which required permits, licenses or other approvals must be obtained:

Long-term care nursing facilities are already required to be licensed in the Commonwealth. This final-form rulemaking will not alter that requirement and all statutory timeframes for licensure will remain in effect.

(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.

The Department regularly reviews the validity and efficacy of its regulations and will continue to do so in the future and as needs arise. In addition, the Department will be providing technical assistance and outreach to the regulated community to assist with implementation of this final-form regulation.

DEPARTMENT OF HEALTH, FINAL-FORM REGULATION # 10-223

RULEMAKING 3 — APPLICATIONS FOR OWNERSHIP, MANAGEMENT AND CHANGES OF OWNERSHIP;
HEALTH AND SAFETY

EXHIBIT “A”

Commonwealth of Pennsylvania
Department of Health
NURSING HOME LICENSURE APPLICATION

<p>Name of Facility _____ (Doing Business As)</p> <p>Address _____ Street</p> <p>City _____ Zip _____</p> <p>County _____ Area Code _____ Telephone No. _____</p> <p>E-mail _____</p> <p>Name of Immediate Owner (Licensee) _____</p>	<p>Type of Application:</p> <p><input type="checkbox"/> Renewal <input type="checkbox"/> Change of Ownership <input type="checkbox"/> New Facility <input type="checkbox"/> Change of Beds <input type="checkbox"/> Change of Name</p> <p>Provisional: <input type="checkbox"/> Provisional to Regular: <input type="checkbox"/></p> <p>Type of Ownership:</p> <p><input type="checkbox"/> Individual <input type="checkbox"/> City/County Government</p> <p><input type="checkbox"/> Partnership <input type="checkbox"/> Hospital Based</p> <p><input type="checkbox"/> Corporation <input type="checkbox"/> State Government</p> <p>Type of Operation:</p> <p><input type="checkbox"/> Profit <input type="checkbox"/> Non-profit</p>
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Have you increased your bed capacity by 10% or more, or by 10 beds, whichever is greater, within the last 2 years? yes no

If yes, give year of change _____ Current beds _____ Prior beds _____

Current Licensed Capacity: _____ Requested Capacity: _____

Current License Number: _____ Expiration Date of Current License: _____

Name of Administrator _____	License Number _____
Name and Address of Applicant _____	Area Code _____ Telephone No. _____

Are there any directors, officers, agents, or managing employees of the institution, agency or organization who have ever been convicted of a criminal offense related to their involvement in such programs established by Titles XVIII, XIX, or XX? yes no

Has there been a change in ownership or control within the last year? If yes, give date _____ yes no

Do you anticipate any change of ownership or control within the year? If yes, when? _____ yes no

Do you anticipate filing for bankruptcy within the year? If yes, when? _____ yes no

If county operated or sponsored, enter address of Board of Commissioners and name of commissioners.

Address _____

Name of Commissioner _____	Name of Commissioner _____	Name of Commissioner _____
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<p>Is the facility and/or building- owned <input type="checkbox"/> leased <input type="checkbox"/></p> <p>If leased, list the name and address of lessor. _____</p>	<p>Is the facility managed by an organization other than licensee? yes <input type="checkbox"/> no <input type="checkbox"/></p> <p>If yes, list the name and address of the organization. _____</p>
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<p>List <u>name</u> and <u>address</u> of all persons having ownership of 5% or more. (Attach additional sheet if necessary)</p>	<p>If appropriate, list the <u>name</u> and <u>address</u> of <u>trustees</u> or <u>board members</u>. (Attach additional sheet if necessary)</p>
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Commonwealth of Pennsylvania
Department of Health
NURSING HOME LICENSURE APPLICATION

Are there any individuals or organizations having a direct or indirect ownership or control interest of 5 percent or more in the institution, organizations, or agency that have been convicted of a criminal offense related to the involvement of such persons, or organizations in any of the programs established by Titles XVIII, XIX, or XX? Yes No

Are there any individuals currently employed by the institution, agency, or organization in a managerial, accounting, auditing, or similar capacity who were employed by the institution's organization's, or agency's fiscal intermediary or carrier within the previous 12 months? (Title XVIII providers only) Yes No

Is the facility's ownership involved with a pyramid or parent corporate structure? Yes No
If applicable, list name and address of parent corporation or pyramid corporate structures. Explain as necessary.

Does owner(s) or corporate members have financial interest in other health care facilities? Yes No
If yes, list name and address of all other health care facilities in which the owner or corporate members have financial interest. (Attach additional sheet if necessary)

PAYMENT

A CHECK OR MONEY ORDER PAYABLE TO COMMONWEALTH OF PENNSYLVANIA FOR THE AMOUNT OF THE FEE MUST ACCOMPANY THIS APPLICATION. CURRENCY IS NOT ACCEPTABLE. THE REGULAR FEE PER LICENSE IS \$250.00 PLUS \$2.00 FOR EACH BED IN EXCESS OF 75 BEDS.

The fee per license for a provisional license is as follows:

- First provisional - \$400.00 + \$4.00 per bed
- Second provisional - \$600.00 + \$6.00 per bed
- Third provisional - \$800.00 + \$8.00 per bed
- Fourth provisional - \$1000.00 + \$10.00 per bed

The licensure fee for the next license amounts to \$_____ . Mail check or money order, along with the completed application and any amendments or changes to the Pennsylvania Department of Health, Division of Nursing Care Facilities, Room 526, Health and Welfare Building, Harrisburg, PA, 17120.

AGREEMENT

Application is made to operate a long-term care facility in accordance with the Health Care Facilities Act (35 P.S. §448.101 - 448.904).

I agree that all of the above information is COMPLETE and true. Incomplete or inaccurate information IS REASON FOR NON-RENEWAL OF THE FACILITY'S LICENSE. I further agree to conduct said facility in accordance with the laws of the Commonwealth of Pennsylvania and with the rules and regulations of the Department of Health.

AFFIDAVIT

Commonwealth of Pennsylvania

County of _____

_____ being duly sworn according to the law deposes and says that the facts set forth in the forgoing application are true, correct, and complete to the best of my knowledge, information, and belief.

Signed _____

Sworn to and subscribed before me this _____ day of _____, 20_____.

My commission expires _____

(Signature - Notary Public)



COMMONWEALTH OF PENNSYLVANIA
OFFICE OF THE SECRETARY OF HEALTH

September 27, 2022

Mr. David Sumner
Executive Director
Independent Regulatory Review Commission
14th Floor, 333 Market Street
Harrisburg, PA 17101

Re: Department of Health – Final Regulation No. 10-223
Long-Term Care Nursing Facility Regulations
28 Pa. Code §§ 201.12—201.17, 201.22, 209.1, 209.7, 209.8 and 211.1
Rulemaking 3 – Application for Ownership, Management and Changes of Ownership;
Health and Safety

Dear Mr. Sumner:

Enclosed are final-form regulations for review by the Independent Regulatory Review Commission (IRRC) in accordance with the Regulatory Review Act (71 P.S. §§ 745.1—745.15). This is the third of four rulemaking packages that amend Subpart C (relating to long-term care facilities) of Part IV of Title 28 of the Pennsylvania Code. Subpart C consists of 6 different chapters: Chapters 201, 203, 205, 207, 209 and 211. The purpose of this final-form rulemaking is to create consistency between Federal and State requirements for long-term care nursing facilities by updating and eliminating provisions that are outdated and duplicative of the Federal requirements to include the requirements set forth at 42 CFR Part 483, Subpart B (relating to requirements for long-term care facilities). This final-form rulemaking also updates: (1) State requirements for applications for licensure and ownership of a facility; and (2) responsibilities for licensees, including a quarterly facility assessment.

The Regulatory Review Act provides that upon completion of the agency's review of comments following proposed rulemaking, the agency is to submit to IRRC and the Standing Committees of the General Assembly a copy of the agency's response to the comments received, the names and addresses of the commentators who have requested additional information relating to the final-form regulations, and the text of the final-form regulations which the agency intends to adopt. *See* 71 P.S. §§745.5a(a).

A list of the names and addresses of the commentators who requested a copy of the final-form regulations is enclosed. The Department previously forwarded these comments to the Commission.

The Act also provides that IRRC may have until its next scheduled meeting which occurs no less than 30 days after receipt of the final-form regulation to approve or disapprove the final-form regulation. 71 P.S § 745.5a(e).

The Department will provide IRRC with any assistance it requires to facilitate a thorough review of the regulations. If you have any questions, please contact David Toth, Director of the Office of Legislative Affairs, at (717) 787-6436.

Sincerely,

A handwritten signature in cursive script, appearing to read "Denise Johnson".

Denise Johnson, MD
Acting Secretary of Health

Enclosures

CDL-1

**FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU
(Pursuant to Commonwealth Documents Law)**

RECEIVED

SEP 27 2022

Independent Regulatory
Review Commission

DO NOT WRITE IN THIS SPACE

<p>Copy below is hereby approved as to form and legality. Attorney General</p> <p>BY: _____ (DEPUTY ATTORNEY GENERAL)</p> <p>_____</p> <p>DATE OF APPROVAL</p> <p><input type="checkbox"/> Check if applicable Copy not approved. Objections attached.</p>	<p>Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:</p> <p>Department of Health (AGENCY)</p> <p>DOCUMENT/FISCAL NOTE NO. <u>10-223</u></p> <p>DATE OF ADOPTION: _____</p> <p>BY: <u>Denise Johnson, M.D.</u></p> <p></p> <p>_____</p> <p>TITLE: <u>Acting Secretary of Health</u> (EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)</p>	<p>Copy below is hereby approved as to form and legality. Executive or Independent Agencies.</p> <p>BY: </p> <p>_____</p> <p>September 27, 2022</p> <p>DATE OF APPROVAL</p> <p>Deputy General Counsel (Chief Counsel, Independent Agency) (Strike inapplicable title)</p> <p><input type="checkbox"/></p> <p>Check if applicable. No Attorney General approval or objection within 30 days after submission.</p>
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NOTICE OF FINAL RULEMAKING

DEPARTMENT OF HEALTH

TITLE 28. HEALTH AND SAFETY

PART IV. HEALTH FACILITIES

SUBPART C. LONG-TERM CARE FACILITIES

28 PA. CODE §§ 201.12—201.17, 201.22, 209.1, 209.7, 209.8 and 211.1

RULEMAKING 3 — APPLICATIONS FOR OWNERSHIP, MANAGEMENT AND CHANGES OF OWNERSHIP; HEALTH AND SAFETY

The Department of Health (Department), after consultation with the Health Policy Board, amends 28 Pa. Code §§ 201.12—201.17, 201.22, 209.1, 209.7, 209.8 and 211.1 and adds §§ 201.12a, 201.12b, 201.13a, 201.13b, 201.13c, 201.15a and 201.15b to read as set forth in Annex A. This is the third of four final-form rulemaking packages for long-term care nursing facilities being promulgated by the Department.

The contents for the four final-form rulemaking packages are as follows:

Rulemaking 1 – General Applicability and Definitions

§ 201.1. Applicability.

§ 201.2. Requirements.

§ 201.3. Definitions.

Rulemaking 2 – General Operation and Physical Requirements

§ 201.23. Closure of facility.

Chapter 203. Application of Life Safety Code for Long-Term Care Nursing Facilities. (Reserved on final-form).

Chapter 204. Physical Environment and Equipment Standards for Construction, Alteration or Renovation of Long-Term Care Nursing Facilities After July 1, 2023.

Chapter 205. Physical Environment and Equipment Standards for Long-Term Care Nursing Facilities Construction, Alteration or Renovation Approved before July 1, 2023.

§ 207.4. Ice containers and storage. (Reserved on final-form).

Rulemaking 3 – Applications for Ownership, Management and Changes of Ownership; Health and Safety

§ 201.12. Application for license of a new facility or change in ownership.

§ 201.12a. Notice and opportunity to comment (New Section on final-form)

§ 201.12b. Evaluation of application for license of a new facility or change in ownership. (Section renumbered on final-form)

§ 201.13. Issuance of license for a new facility or change in ownership.

§ 201.13a. Regular license. (New Section on final-form)

§ 201.13b. Provisional license. (New Section on final-form)

§ 201.13c. License renewal. (Section renumbered on final-form)

§ 201.14. Responsibility of licensee.

§ 201.15. Restrictions on license.

§ 201.15a. Enforcement. (New Section on final-form)

§ 201.15b. Appeals. (New Section on final-form)

§ 201.17. Location.

§ 201.22. Prevention, control and surveillance of tuberculosis (TB).

§ 209.1. Fire department service. (Reserved on final-form).

§ 209.7. Disaster preparedness. (Reserved on final-form).

§ 209.8. Fire drills. (Reserved on final-form).

§ 211.1. Reportable diseases.

Rulemaking 4 – Qualifications, Training, Job Duties, Recordkeeping, Program Standards, and Resident Rights and Services

§ 201.18. Management.

§ 201.19. Personnel records.

§ 201.20. Staff development.

§ 201.21. Use of outside resources.

§ 201.24. Admission policy.

§ 201.25. Discharge policy. (Reserved on final-form).

§ 201.26. Resident representative.

§ 201.29. Resident rights.

§ 201.30. Access requirements. (Reserved on final-form).

§ 201.31. Transfer agreement.

§ 207.2. Administrator's responsibility. (Reserved on final-form).

§ 209.3. Smoking.

§ 211.2. Medical director.

§ 211.3. Verbal and telephone orders.

§ 211.4. Procedure in event of death.

§ 211.5. Medical records.

§ 211.6. Dietary services.

§ 211.7. Physician assistants and certified registered nurse practitioners.

§ 211.8. Use of restraints.

§ 211.9. Pharmacy services.

§ 211.10. Resident care policies.

§ 211.11. Resident care plan. (Reserved on final-form).

§ 211.12. Nursing services.

§ 211.15. Dental services.

§ 211.16. Social services.

§ 211.17. Pet therapy.

Comments on Multiple Packages; Stakeholder Engagement

The Department received comments during the public comment periods of all four proposed rulemaking packages expressing concern with the Department's decision to divide the long-term care nursing facility regulations into separate rulemakings. As provided above, the department divided the regulatory packages as follows: Rulemaking 1 – *General Applicability and Definitions*; Rulemaking 2 – *General Operation and Physical Requirements*; Rulemaking 3 – *Applications for Ownership, Management and Changes of Ownership; Health and Safety*; and Rulemaking 4 – *Qualifications, Training, Job Duties, Recordkeeping, Program Standards, and Resident Rights and Services*.

Although the Department intended to provide succinct areas for review and comment, commentators expressed some difficulty in reviewing sections of the regulations without the context of the remaining regulatory chapters and concern that multiple regulatory packages may lead to a lack of clarity and confusion for the regulated community and the public. Commentators also requested that the Department consider comments on all four proposed rulemaking packages outside of the 30-day comment period for each proposed package, or that the Department withdraw or resubmit all four proposed rulemaking packages as one package with an additional 30-day comment period. The Department also received comments regarding concern related to recent engagement with stakeholders, given that the Long-term Care Work Group last formally met in 2018 and was disbanded during the start of the COVID-19 pandemic.

In commenting on proposed Rulemaking 1, the Independent Regulatory Review Commission (IRRC) acknowledged the Department's authority to promulgate regulations as it deems appropriate. However, IRRC requested the Department to consider the regulated community's comments and the requests regarding the separate rulemakings. IRRC specifically asked the Department to explain why its approach in dividing the amendments into multiple packages was reasonable. IRRC also asked that the Department ensure that amendments be consistent across the packages, and that the interrelation and any impacts between the packages be clearly presented for the regulated community.

In commenting on proposed Rulemaking 2, IRRC again echoed concerns that separate rulemakings have the potential consequence of inconsistencies and errors across the four packages. IRRC inquired whether having multiple regulatory packages is in the public interest, whether it protects the public health, safety, and welfare, and whether it is reasonable and lacks ambiguity. IRRC asked whether it was in the public interest or reasonable to expect the regulated community to hold multiple proposed regulations simultaneously in mind while reviewing a proposed regulation. IRRC also asked the Department to: (1) identify in the final-form preamble any provisions which assume approval of Rulemaking 1 as final-form; (2) cross-reference these provisions to the relevant provisions in Rulemaking 1; and (3) explain the impact if Rulemaking 1 is not approved before or at the same time as rulemaking 2. IRRC

recommended that the Department deliver each of the four individual packages as final-form regulations on the same day. In addition, IRRC, in its comment for proposed Rulemaking 3 and Rulemaking 4 expressed the same concerns as in the previous proposed rulemakings, but additionally suggested that the Department consider issuing an Advance Notice of Final Rulemaking (ANFR) to assist in reaching consensus.

Response

At the outset, the Department recognized that the changes to the long-term care nursing facility regulations would be numerous and complex, whether presented in one giant package or in multiple packages. A large single package would have been unwieldy and would likely have been presented around the date that the fourth regulatory package was completed and submitted (May 11, 2022). A later publication date would have resulted in less opportunity for comments, less time for the commentators to study the material and deliberate, and less time for necessary and valuable stakeholder engagement. Further, the regulated community's input throughout this process informed the administration and legislature's investment in this year's budget. As such, the decision was made to continue with the changes into smaller, separate more digestible package. As provided above, the Department initially decided to divide the proposed amendments to the six regulatory chapters under Subpart C (relating to long-term care facilities) into multiple packages to allow the public and interested parties a greater opportunity to thoroughly examine and digest the distinct proposed regulatory amendments over a longer period. In dividing these six chapters over four rulemakings, the public and interested parties would be permitted to provide more detailed comments and allow the Department to focus more closely on comments, provide a thoroughly considered response to questions and comments, and tailor the remaining proposed packages based on additional public and stakeholder input.

Further, in response to these public comments, the Department has considered all public comments and IRRC's comments across all four proposed rulemakings before drafting the four final-form rulemakings. In addition, based on comments received, the Department is submitting all four final-form rulemakings to IRRC, the legislative standing committees and the public commentator together on the same day. The drafting and submitting all four final-form rulemakings together at the end of the last public comment periods allows interested parties and the public to vet and comment on each package separately, as well as in relation to the other packages. Throughout this process, the Department has continued to accept and review comments and be available to meet with stakeholders. If a commentator believed that a proposed amendment in Rulemaking 4 did not align with a proposed amendment in Rulemaking 1, the commentator could submit a comment to that effect for consideration by the Department during the public comment period for the proposed Rulemaking 4.

The Department did, in fact, take into consideration comments received on proposed Rulemakings 1 and 2, when drafting proposed Rulemakings 3 and 4. This is as evidenced by the proposal to expressly include text from the Centers for Medicare & Medicaid (CMS), *State Operations Manual, Appendix PP* into the text of the regulation. *See e.g.*, Proposed Rulemaking 4, Proposed § 201.29(o) (relating to resident's rights). This inclusion of specific text was based on comments received by commentators and IRRC in proposed Rulemaking 1. The Department also consolidated the total number of proposed packages from five to four packages in response to both public and IRRC comments received in proposed Rulemaking 1.

In addition to considering comments on the four proposed packages during and outside of the four public comment periods, the Department met with stakeholders on four occasions following the receipt of public comments to discuss their concerns and to gain additional insight into comments that were received. The first of these meetings, for proposed Rulemakings 1 and 2, occurred on December 15, 2021. Representatives from AARP, Alzheimer's Association – Delaware Valley and Greater Pennsylvania Chapters, Center for Advocacy for the Rights & Interests of the Elderly (CARIE), Community Legal Services, LeadingAge, Pennsylvania Health Care Association (PHCA), Pennsylvania Coalition of Affiliated Healthcare & Living Communities (PACAH), and SEIU Healthcare Pennsylvania attended that meeting. The second meeting, for proposed Rulemaking 3 occurred on June 8, 2022. Representatives from AARP, Alzheimer's Association, CARIE, Community Legal Services, LeadingAge, PHCA, Pennsylvania Health Law Project (PHLP), and SEIU again attended that stakeholder meeting. The Department explicitly stressed to stakeholders during this June 8, 2022, meeting that it would be considering comments on all proposed rulemakings, and that it would welcome any additional comments or feedback that stakeholders might have after the meeting regarding proposed amendments to the various regulatory chapters. The Department also indicated in a press release on proposed Rulemaking 4, issued on June 3, 2022, that it would be considering comments on all four proposed rulemakings before submitting final-form regulations. The third meeting with stakeholders, for proposed Rulemaking 4, occurred on August 3, 2022. Present at that meeting were representatives from AARP, Alzheimer's Association, CARIE, PHCA, Pennsylvania Health Funders Collaborative (PHFC), and SEIU. The Department held the fourth meeting on August 17, 2022. At this meeting, the Department presented stakeholders with an overview of the changes that were made from proposed to final-form in response to their comments, on all four rulemakings, and provided them with an opportunity to comment and provide feedback on the final-form regulations. Present at that meeting were representatives from the Alzheimer's Association, CARIE, Community Legal Services, County Commissioners Association (CCAP), Disability Rights, LeadingAge, PHCA, PHFC, and SEIU.

After consideration of all comments received on the four proposed packages, the Department firmly supports its decision in splitting the six long-term care nursing facility chapters into multiple packages. While the Department appreciates the comments and suggestion for one consolidated package, one is not needed at this stage due to the public, the regulated community, and advocates full and continued opportunity to offer input on all the long-term care nursing facilities' regulations, throughout the four separate public comment periods, the first of which occurred over a year ago, as well as during the stakeholder meetings that occurred from 2021 through August 2022. In addition, as mentioned previously, at the meeting on August 17, 2022, the Department provided stakeholders an overview of the changes that were adopted on all four rulemakings, to ensure that stakeholders fully understand all amendments. At that meeting, the Department also permitted stakeholders the opportunity to further comment on the final-form amendments and incorporated this feedback into the final-form regulations. Finally, as noted above, splitting the regulations into multiple, separate packages benefited the public, regulated community, and advocates because it allowed the Department to incorporate their feedback as it moved forward with the drafting of subsequent packages, which promoted the public interest, health, safety, and welfare by improving the overall quality of the proposed regulations.

The Department has, in each of the four final-form preambles, discussed and responded to all comments received on the contents of the four proposed rulemakings, regardless of when the comment was received. The Department has added cross-references, as appropriate, where comments received on one package relate to another package to further aid in the review of the four packages together in their entirety. For example, in proposed Rulemaking 1, the Department received comments requesting that staff, other than nursing personnel, be considered when determining whether a facility has met the minimum number of direct resident care hours in § 211.12(a)(i) (relating to nursing services). In response to this comment, the types of individuals required for the minimum number of direct resident care hours was intentionally addressed in proposed Rulemaking 4 and generated additional comments during that proposed rulemaking's public comment period. The Department has, therefore, indicated in § 211.12(i) of the preamble for final-form Rulemaking 1, that it received comments on this topic and provided a cross-reference to the more in-depth discussion of this topic in the preamble for final-form Rulemaking 4. Further, to provide additional clarity and readability, the Department moved the proposed language relating to direct resident care hours from proposed Rulemaking 1 to the final-form Rulemaking 4 - *Qualifications, Training, Job Duties, Recordkeeping, Program Standards, and Resident Rights and Services*. Finally, the Department has noted where one rulemaking assumes the approval of another rulemaking. Through this extended review and public comment process, the Department has been transparent in its proposals and has responded to these comments through each rulemaking.

Background and Need for Amendments

The percentage of adults 65 years of age or older in this Commonwealth is increasing. In 2010, approximately 15% of Pennsylvanians were aged 65 or older. In 2017, this number increased to 17.8%. In 2020, just under 20 percent of the population in Pennsylvania was 65 years of age or older. For every 10 individuals under 25 years of age lost in Pennsylvania since 2010, the state gained 21 persons aged 65 or older. This Commonwealth also has a higher percentage of older adults when compared to other states. In 2017, this Commonwealth ranked fifth in the Nation in the number (2.2 million) of older adults and seventh in percentage (17.8%). The increase in older Pennsylvanians is expected to continue. It has been estimated that by 2030, there will be 38 older Pennsylvanians (65 years of age or older) for every 100-working age Pennsylvanians (15 years of age to 64 years of age). Penn State Harrisburg, Pennsylvania State Data Center. (July 2018). Population Characteristics and Change: 2010 to 2017 (Research Brief). Retrieved from <https://pasdc.hbg.psu.edu/data/research-briefs/pa-population-estimates>; Penn State Harrisburg, Pennsylvania State Data Center. (July 2018). (June 2022). Trends in Pennsylvania's Population by Age. (Research Brief). Retrieved from https://pasdc.hbg.psu.edu/sdc/pasdc_files/researchbriefs/June_2022.pdf.

As the number of older Pennsylvanians increases, the number of those needing long-term care nursing will also increase. It has been estimated that an individual turning 65 years of age today has an almost 70% chance of needing some type of long-term services or support during the remainder of their lifetime; 20% will need long-term care support for longer than 5 years. More people use long-term care services at home and for longer; however, approximately 35%

utilize nursing facilities for this type of care. Administration for Community Living. (February 2020). How Much Care Will You Need? Retrieved from <https://acl.gov/ltc/basic-needs/how-much-care-will-you-need>. Approximately 72,000 individuals reside in the 682 long-term care nursing facilities currently licensed by the Department.

The COVID-19 pandemic highlighted the vulnerability of older adults, with a larger percentage of deaths occurring in individuals 65 years of age and older. Centers for Disease Control and Prevention (CDC). Demographic Trends of COVID-19 Cases and Deaths in the US Reported to CDC. Retrieved from <https://covid.cdc.gov/covid-data-tracker/#demographics>. See also, CDC. COVID-19 Weekly Cases and Deaths per 100,000 Population by Age, Race/Ethnicity and Sex, United States, March 1, 2020—June 25, 2022. Retrieved from <https://covid.cdc.gov/covid-data-tracker/#demographicsovertime>. Further, it is estimated that at least a quarter of COVID-19 deaths occurred in long-term care nursing facilities. The COVID Tracking Project. (March 2021). Long-Term-Care COVID Tracker. Retrieved from <https://covidtracking.com/nursing-homes-long-term-care-facilities>. In this Commonwealth alone, there have been approximately 11,443 confirmed deaths of residents in long-term care nursing facilities since January 2020. AARP. (September 15, 2022). AARP Nursing Home COVID-19 Dashboard Fact Sheets. Retrieved from <https://www.aarp.org/ppi/issues/caregiving/info-2020/nursing-home-covid-states.html>.

The repercussions of the pandemic have reached far beyond the direct, physical effects of contracting the COVID-19 virus. Lockdowns intended to protect vulnerable residents at the beginning of the pandemic led to social isolation and loneliness because residents were prevented from having in-person contact with their loved ones. This led to an increase in depression and anxiety, cognitive decline and in some cases, physical deterioration, among residents who were already fearful of contracting the virus. Levere, M., Rowan, P., & Wysocki, A. (2021). "The Adverse Effects of the COVID-19 Pandemic on Nursing Home Resident Well-Being." *Journal of the American Medical Directors Association*, 22(5), 948-954.e2. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7980137/>. Nursing service personnel, who were already stressed before the pandemic, incurred additional stress from, among other things, shortages in personal protective equipment (PPE), limited access to COVID-19 testing supplies, fear of contracting COVID-19 while at work and spreading it to others, concern for residents under their care, lack of public support and recognition, and an increase in workloads due to the additional protective measures needed to prevent spread of COVID-19 and other nursing service personnel leaving the workforce. White, E.M., Wetle, T.F., Reddy, A. & Baier, R.R. (2021). "Front-line Nursing Home Staff Experiences During the COVID-19 Pandemic." *Journal of the American Medical Directors Association*, 22(1), 199-203. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7685055/>.

The Department's long-term care nursing facilities regulations have not been updated since 1999, with the last significant update occurring in 1997 after the 1996 amendment to the Health Care Facilities Act (the HCFA or act) (35 P.S. §§ 448.101—448.904b). Since that time, there have been substantial changes in the means of delivering care and providing a safe environment for residents in long-term care nursing facilities, with the pandemic further highlighting the need for change. The Department has been attempting to complete this much needed reform since before the pandemic, in late 2017. At that time, the Department sought assistance and advice from members of a long-term care work group (LTC Work Group). The

Department worked with the LTC Work Group regularly in 2018. The members of the LTC Work Group were drawn from a diverse background and included representatives from urban and rural long-term care facilities and various stakeholder organizations and consumer groups that work in the area of resident care and delivery of services. The LTC Work Group members consisted of representatives from the following organizations: American Institute of Financial Gerontology; Baker Tilly Virchow Krause, LLP; Berks Heim and Rehabilitation; Fulton County Medical Center; Garden Spot Community; HCR ManorCare; Inglis House; Landis Communities; Leading Age; Legg Consulting Services; LIFE Pittsburgh; Luzerne County Community College; The Meadows at Blue Ridge; Mennonite Home, Lutheran Senior Life Passavant Community; PA Coalition of Affiliated Healthcare and Living Communities; Pennsylvania Home Care Association; University of Pittsburgh; and Valley View Nursing Home. The following State agencies participated: Department of Aging; the Department of Human Services (DHS); and the Department of Military and Veteran's Affairs (DMVA).

The members of the LTC Work Group met regularly during 2018 with the LTC Work Group's primary focus being the simplification and modernization of the existing long-term care regulations. After these discussions were complete, the Department reviewed the recommendations of the LTC Work Group and consulted with other potentially impacted agencies in 2019 and 2020. In 2020, 2021 and 2022, the Department continued its efforts to draft amendments to the long-term care nursing facility regulations while also handling the day-to-day challenges of protecting the residents of those facilities, who were being hit the hardest by the COVID-19 pandemic.

As discussed previously, in response to concerns raised by IRRC and commentators, the Department ramped up its communications with stakeholders by holding the first of four stakeholder meetings, beginning in December 2021, to address comments received on proposed Rulemakings 1 and 2. The Department held a second meeting with stakeholders in June 2022 after the public comment and IRRC comment periods ended for proposed Rulemaking 3, and a third stakeholder meeting in August 2022 after the public and IRRC comment periods ended for proposed Rulemaking 4. The Department held a fourth stakeholder meeting on August 17, 2022, to provide an overview of changes from proposed to final-form and permitted stakeholders to provide additional feedback and comments on amendments during this meeting.

The discussions with stakeholders and the comments received on the four proposed rulemakings have made it abundantly clear that amendments to the current long-term care nursing facility regulations are desperately needed and must not be delayed any longer. Commentators expressed in comments to all four groups that they were pleased to see the Department updating these regulations. The comments in support of amending the regulations can generally be summarized as follows:

- Amendments are long overdue.
- Revisions to existing regulations are urgently needed.
- COVID-19 had a devastating impact on facilities and highlighted the need for revisions.
- Regulations need to be updated to provide additional protections to residents.

Unfortunately, while commentators agree for the most part that an update to the regulations is needed, they do not agree on the extent of the update needed. Some commentators

strongly argued that the Department's proposed amendments do not go far enough in protecting residents, while other commentators strongly argued that the Department's proposed amendments go too far and result in a fiscal impact. The Department has considered all comments it received both in favor of and against the proposed amendments and has responded to those comments. In considering those comments and balancing the competing interest of the parties in this regulatory review process, the Department has made revisions from the proposed rulemakings to the final-form rulemakings. The Department has also provided explanations to comments received in the preambles for each of the four final rulemakings, as explained more fully above.

Public Comments

In response to proposed Rulemaking 3, the Department received comments from 12 public commentators, seven form letters, one legislative letter from Senator Collett, the co-chair of the Senate Aging and Youth Committee, and comments from IRRC. These comments are discussed in further detail below.

Description of Amendments / Summary of Comments and Responses

Amendments related to applications for licensure for new facilities and changes in ownership for existing facilities

As noted on proposed, the Department has seen a shift in ownership of long-term care nursing facilities, making it difficult to vet prospective owners of these types of facilities under the existing requirements. Specifically, over the past 20 years, the Department has seen a shift in ownership from non-profit entities to for-profit entities. It has been estimated that nationwide, approximately 70 percent of long-term care nursing facilities are owned by for-profit entities. Gupta, A., et. al. "Does Private Equity Investment in Healthcare Benefit Patients? Evidence from Nursing Homes." (February 2021). Retrieved from https://bfi.uchicago.edu/wp-content/uploads/2021/02/BFI_WP_2021-20.pdf (hereinafter Gupta study).

The ownership structure of for-profit entities has also become increasingly complex as owners have sought to protect themselves from liability. Complex ownership structures make it difficult to determine exactly who owns the facility, who owns the real property that the facility occupies, and most importantly, who exactly is responsible for the care of residents in the facility. This makes it difficult for residents, their families, and even regulators to hold owners accountable for the health and safety of residents. Private equity firms, in particular, have recently become interested in owning long-term care nursing facilities. Private equity firms are known for conducting leveraged buyouts, in which an entity is purchased by borrowing the cash needed to make the purchase. In the case of long-term care nursing facilities, private equity owners will often sell the facility's real estate assets shortly after the buyout to generate cash for their investors. This results in the need to pay rent. These rental payments, in addition to the debt incurred during the buyout, reduces the amount of cash available to provide for the care of residents. See Gupta study. This lack of cash can have dire consequences for residents in long-term care nursing facilities, as the facility is forced to cut costs, often by reducing staff. In some cases, the facility may end up closing due to its failure to meet its debt obligations, leaving residents scrambling to find care elsewhere. The Commonwealth and the Department experienced firsthand, with the well-publicized Skyline Healthcare collapse, the detrimental

impact a business failure can have on residents of a long-term care nursing facility. Strickler, L., et al. (July 2019). "A nursing home grows too fast and collapses, and elderly and disabled residents pay the price." Retrieved from <https://www.nbcnews.com/health/aging/nursing-home-chain-grows-too-fast-collapses-elderly-disabled-residents-n1025381> Marselas, K. (May 2018). "Skyline's implosion continues with Pennsylvania takeover." Retrieved from <https://www.mcknights.com/news/skylines-implosion-continues-with-pennsylvania-takeover/>.

The Department has spent the past several years investigating the best way to evaluate prospective owners of long-term care nursing facilities to protect the health and safety of residents and to prevent such a recurrence. The Department has determined that the best way to accomplish this is through the application for licensure process. The application process provides the Department with the opportunity to gather information into the background of a prospective owner. Having as much information as possible regarding the background of a prospective owner will aid the Department in vetting prospective owners to determine whether they are a responsible person under the HCFA. For example, information pertaining to financial stability, corporate history, regulatory history in other jurisdictions, and prospective plans for the management of the facility all provide insight into a person's ability to operate a long-term care nursing facility. This insight is vital in determining whether a person can provide the care necessary for residents in a long-term care nursing facility.

The Department amended several provisions to update and clarify the licensure process for new facilities and to address changes in ownership of existing facilities. The response from commentators to the proposed amendments was overall positive, although some commentators suggested additional amendments. These comments are addressed in each section below.

§ 201.12. Application for license of a new facility or change in ownership

The title of this section is unchanged from proposed to final-form. The Department proposed to add "of a new facility or change in ownership" to the title of this section. As explained on proposed, the Department has always required the submission of an application under existing § 201.12 for changes in ownership for already existing facilities, in addition to new facilities. To eliminate confusion, the Department is adding "a new facility or change in ownership" to the title of this section to clarify that the same application process applies to both new long-term care nursing facilities and changes in ownership for already existing facilities.

Commentators requested that the Department clarify what is meant by the term "person" and to include a definition for the term "person" in § 201.3 (relating to definitions) with a cross-reference to the definition of this term in the act. To assist readers, the Department has added a definition for the term "person" to § 201.3 (relating to definitions), in final-form Rulemaking 1—*General Applicability and Definitions*, with a specific cross-reference to the definition of that term in HCFA. The use of the term "person" in this section refers to this definition. For clarity, the Department also uses the term "prospective licensee" in this section to describe a person who seeks to own or operate a facility. The Department has made this amendment throughout § 201.12, as noted below.

Commentators also suggested that the Department impose a timeline on the application for licensure process. One commentator recommended that a final determination on an application for licensure occur within 30 days from the date the application is submitted.

Another commentator suggested the following timeline for changes in ownership: an initial review of the selling facility for stability and resident well-being within 5 days of receiving an application for licensure; a temporary determination issued to the selling facility within 10 business days; full document submission by the purchasing facility within 10 days of the application; 15 business days for the Department to request additional documentation; and a final determination within 30 days the application is submitted. IRRC also inquired whether there will be set timelines for review of the application and documents submitted under § 201.12 and for a decision to be made on the application.

First, in response to the commentator who requested that the Department place deadlines on a selling facility, the Department notes that the purchasing facility (prospective licensee), not the selling facility, is responsible for obtaining a license by following the application process under § 201.12. Under § 201.12(a.2), the prospective licensee must submit to the Department, at the same time, the application form and fee and the other items delineated in subsections (b) and (e). Under 28 Pa. Code § 51.4 (relating to change in ownership; change in management), a facility must notify the Department at least 30 days prior to a change in ownership. Therefore, the prospective licensee must submit the application form, fee and other items required under § 201.12 at least 30 days prior to the change in ownership. The Department will conduct its review of all items submitted under § 201.12, as well as comments received during the 10-day public comment period, concurrently. The Department, however, sees no advantage or benefit in breaking its review up with a temporary determination, as suggested by the commentator, and believes that doing so could confuse prospective licensees and others, who may mistakenly believe that a temporary determination is final.

In response to commentators who requested the Department implement a timeline for the application of licensure process generally, and in response to IRRC's question as to whether there will be set timelines for review of the application, the Department notes that it strives to review applications for licensure quickly and in a timely fashion, to ensure the health, safety, and welfare of residents. However, based on departmental experience, the Department can foresee circumstances in which review of applications may be stalled due to delays in receiving completed applications and additional requested information from applicants. The Department therefore declines to place, in regulation, a time limit on its review of applications. Due to the need to ensure the health, safety and welfare of residents in reviewing and approving applications, the Department declines to make this change. The Department makes every effort to work with applicants when there is a delay in the review process, to ensure that the delay is resolved quickly and efficiently.

Subsection (a)

This subsection remains deleted on final-form. As explained on proposed, the Department is deleting this subsection and replacing it with new subsections (a.1) and (a.2) described as follows.

Subsection (a.1)

This subsection is unchanged from proposed to final-form. As explained on proposed, the Department moves the first sentence from § 201.13(a) (relating to issuance of license for a new facility or change in ownership) into this subsection, with amendments. Specifically, the

Department replaces the words "maintain or operate a facility" with the words "operate or assume ownership of a facility." The Department deletes the word "maintain" because renewals of licenses for existing facilities will be addressed separately in new § 201.13c (relating to license renewal). The Department is moving this language to § 201.12 to make it clear that all persons who wish to operate or assume ownership of a long-term care nursing facility must first obtain a license from the Department.

Subsection (a.2)

Subsection (a.2) is amended from proposed to final-form. The Department proposed to move the second sentence from existing subsection (a) into this subsection, with amendments. Specifically, the Department proposed to reword this language to make it clear that a person seeking to operate or assume ownership of a long-term care nursing facility shall obtain an application form from the Division of Nursing Care Facilities in the Department. On final-form, the Department replaces the words "person seeking to operate or assume ownership" with the term "prospective licensee" for consistency in the use of this term to describe a person who seeks to own or operate a facility.

Subsection (b)

Subsection (b) is amended from proposed to final-form. As explained on proposed, subsection (b) specifies information that shall be submitted with the fee and completed application for licensure of a long-term care nursing facility. On final-form, the Department replaces the words "person seeking to operate or assume ownership" with the term "prospective licensee" for consistency in the use of this term to describe a person who seeks to own or operate a facility.

Paragraph (1)

Paragraph (1) is amended from proposed to final-form. The Department proposed several changes to existing paragraph (1), which included an expanded description of the types of persons that the Department considers as having an ownership or control interest in a facility. Commentators asked the Department to clarify what is meant by the term "person" and to clarify whether the definition of a "person" in subparagraphs (i) and (ii) should apply to other paragraphs in subsection (b). In response to these comments, the Department has simplified paragraph (1) on final-form by first, moving the requirement for the names, addresses, e-mail addresses and phone numbers of the facility's officers and members of the board of directors, so that this requirement is listed separately in paragraph (6). The Department has made other grammatical edits to paragraph (1) so that paragraph (1) simply reads as, "the names, addresses, e-mail addresses and phone numbers of any person who has" followed by subparagraphs (i) through (iii).

The Department has also made grammatical edits to subparagraphs (i) and (ii) to include any person who has or will have a direct or indirect ownership interest of 5% or more and any person who holds or will hold the license or ownership interest in the land on which the facility is located or the building in which the facility is located. Further, in response to comments received from commentators, the Department has added a subparagraph (iii), with language that includes any person who "owns or will own a whole or part interest in any mortgage, deed, trust, note or other long-term liability secured in whole or in part by the equipment used in the facility,

the land on which the facility is located or the building in which the facility is located.” Commentators explained at the stakeholder meeting with the Department on June 8, 2022, that this additional information is necessary because ownership structures can be quite complicated, and leases and land fees could be used to extract money from long-term care nursing facilities that should otherwise be spent on resident care. The Department agrees with this suggestion and, therefore, adds this provision on final-form.

Commentators requested that the Department clarify that the definition of a “person” in paragraph (1) applies to other paragraphs in subsection (b). The Department has done so by adding the qualifier “identified in paragraph (1)” after the term “person” where relevant in other paragraphs in subsection (b), described below.

Paragraphs (2) and (3)

Paragraphs (2) and (3) are amended from proposed to final-form. On proposed, the Department proposed to add a requirement for e-mail addresses and phone numbers to the already existing requirement for names and addresses in these two paragraphs. As explained on proposed, expanding the existing requirements in paragraph (2) and (3) to include an e-mail address and phone number will provide the Department with additional means of contacting these individuals. E-mail addresses and phone numbers also tend to be the most effective and efficient way to communicate with individuals. The Department retains these amendments on final-form and replaces the word “the” with the word “a” before the word “person” for grammatical reasons. The Department also adds the words “identified in paragraph (1)” after the word “person” to identify more clearly what is meant by the term “person” in these paragraphs.

Paragraph (4)

Paragraph (4) is unchanged from proposed to final-form. As explained on proposed, the Department adds a requirement that the e-mail address and phone number of the administrator be provided in addition to the administrator’s name, address, and license number. As explained on proposed, expanding the existing requirement in paragraph (4) to include an e-mail address and phone number will provide the Department with additional means of contacting these individuals. E-mail addresses and phone numbers also tend to be the most effective and efficient way to communicate with individuals.

Paragraph (5)

Paragraph (5) is amended from proposed to final-form. The Department proposed to require that prospective licensees provide the names, addresses, e-mail addresses and phone numbers of any persons who have or will have a direct or indirect interest in the management of the facility or the provision of services at the facility. The Department explained that having this information provides the Department with a means of contacting these individuals if there is an issue at the facility. The Department retains this amendment on final-form but with grammatical edits, in response to IRRC’s comment regarding inconsistent tenses. The Department also deletes “or the provision of services at the facility” in response to comment, as explained below.

A commentator asked what the intent is of including “the provision of services” in this paragraph, and what specifically is being asked of prospective licensees. IRRC also asked the Department to clarify what is meant by “provision of services.” In response to these comments,

the Department, on final-form, deletes the words, “or the provision of services at the facility.” The definition of “related party”, as used in paragraph (7), described below, more accurately reflects the Department’s intent to capture information regarding parties who provide a service, facility or supply to the facility.

Paragraph (6)

The language in proposed paragraph (6) is deleted on final-form. The Department had proposed, in paragraph (6), to require that corporate history be submitted with the application. A commentator, and IRRC, requested that the Department clarify what is meant by the term “corporate history.” The Department, in response to this comment, deletes the requirement for a “person’s corporate history.” The additions of paragraphs (7) and (8) on final-form, described below, more accurately reflects the Department’s intent to capture information related to the financial reporting, ownership structure, gross revenues, and identification of related parties of a prospective licensee, with “related party” being defined under subsection (c).

As mentioned previously, the Department, on final-form, moves the requirement that had been proposed in paragraph (1) for the names, addresses, e-mail addresses and phone numbers of the facility’s officers and members of the board of directors, into paragraph (6). This amendment has been made on final-form for clarity and ease of readability.

Paragraph (7)

Paragraphs (7) through (11) are renumbered due to additional requirements being added in paragraphs (7) and (8) on final-form.

Paragraph (7), as amended on final-form, requires a prospective licensee to submit the names, addresses, e-mail addresses, and phone numbers of a parent company, a shareholder and any related party of the persons identified in paragraphs (1) through (6). This requirement is added at the request of public commentators, a legislative comment, and IRRC. Specifically, Senator Collett commented that she was “pleased to see that the Department included language which requires contact information for a person who has or will have ownership or control interests of ‘the license or the land or building occupied and used as the facility.’” She further requested that the Department consider expanding the contact information requirement to include any related business of the owner or operator of the facility which conducts business with any level of the corporate structure of the facility, its parent or related businesses, the building, or the land on which the facility operates.

The Department has defined a “related party” under subsection (c) as a person that provides a service, facility or supply to the facility or that is under common ownership or control, as defined under 42 CFR 413.17(b) (relating to cost to related organizations). The term includes: a home office; a management organization; an owner of real estate; an entity that provides staffing, therapy, pharmaceutical, marketing, administrative management, consulting, insurance or similar services; a provider of supplies or equipment; a financial advisor or consultant; a banking or financial entity; a parent company, holding company or sister organization.

Paragraph (8)

Public commentators and a legislative comment requested that the Department add a requirement for the submission of annual consolidated financial reports, and to include a parent

organization or related entity providing goods or services in this requirement. Specifically, Senator Collett requested improved financial reporting since taxpayer funds make up more than 60% of the operating revenue of skilled nursing facilities across the Commonwealth. Commentators requested that the Department require that the report be reviewed or audited by a certified public accountant and contain a certification of accuracy. Commentators also requested that the report include a balance sheet showing assets, liabilities and net worth at the end of the fiscal year; a statement of income, expenses and operating surplus or deficit for the annual fiscal period; a statement of ancillary utilization and resident census; a statement detailing resident revenue by payer including but not limited to Medicare, MA and other payers; a statement of cashflows, including but not limited to ongoing and new capital expenditures and depreciation; and a combined financial statement that includes all entities reported in the consolidated financial report, unless the organization is prohibited from including a combined financial statement in a consolidated report pursuant to State or Federal law or regulation or a national accounting standard. Commentators requested that prospective licensees indicate which State or Federal law, regulation or national accounting standard prohibits them from providing a combined financial statement. IRRC requested that the Department amend the final-form regulation to include submission of annual consolidated financial reports, or to explain how the public health, safety, and welfare of residents is protected without this requirement.

A commentator also raised concerns about interlocking private equity fiscal arrangements. This commentator indicated it is critical that the Department have financial information to understand the underlying cash flows and ownership and to assure that adequate funds remain for residents' services and supports. IRRC requested that the Department amend the final-form regulation to require submission of information related to interlocking private equity fiscal arrangements, or to explain how the final-form regulation protects the public health, safety, and welfare of residents.

In response to commentators and IRRC, the Department amends paragraph (8), on final-form, to require a prospective licensee to submit an annual financial report that includes the requirements in paragraphs (i) through (iii). The Department is making this an annual requirement, at the request of commentators and IRRC, by adding language to § 201.13c (relating to license renewal) to require that a facility submit, in addition to the application form and renewal fee, an updated annual financial report that meets the requirements in § 201.12(b)(8). This annual reporting will provide financial transparency of the facility to assess financial viability which could affect patient care and reasonableness of expenses. The Department, however, chose not to use the term "consolidated financial report," as requested by commentators and IRRC to prevent confusion with the use of the term "consolidated financial statement" which is a term of art used in accounting. Instead, the Department uses the term "financial report" without the term "consolidated" and outlines in paragraph (8) what exactly is required for the financial report that is to be submitted by prospective licensees.

In paragraph (8)(i), the Department is requiring submission of audited financial statements prepared in accordance with Generally Accepted Accounting Principles (GAAP), which is the commonly accepted standard for recording and reporting accounting information by accountants. If GAAP requires consolidated financial statements, then consolidated financial statements shall be provided. In response to commentators, the Department has decided not to place into regulation, specific requirements for a balance sheet, a statement of income, expenses

and operating surplus or deficit, a statement of cashflows as these items are already required for financial statements prepared in accordance with GAAP.

In paragraph (8)(ii), the Department is requiring a visual representation of the ownership structure, which shall include parent companies, shareholders, and any related parties of the persons identified in paragraphs (1) through (6). This requirement is added on final-form, at the request of commentators and IRRC. A visual representation of the ownership structure will assist the Department in determining the relationship between a prospective licensee and related businesses, shareholders, and any related parties.

In paragraph (8)(iii), the Department is requiring a supplemental schedule of annual gross revenues, prepared in accordance with GAAP, broken out by payor type. This is added in response to public comments because a financial statement or consolidated financial statement prepared in accordance with GAAP generally would not provide information regarding payor type.

Paragraph (9)

The requirement proposed by the Department in paragraph (7) is moved to paragraph (9) on final-form. The Department makes two grammatical amendments, in response to comment from IRRC regarding inconsistent tenses. The Department adds the word “has” before “had” and deletes the words “of that facility” at the end of the sentence. The Department also replaces the words “any percentage of interest” with the words “a direct or indirect interest of 5% or more” in response to comment from IRRC and a commentator who requested this clarification. The Department adds “long-term care nursing” before the word “facility” in response to a commentator who asked for clarity regarding the standalone term “facility.” The Department also replaces the word “person” with the term “prospective licensee” for consistency in the use of this term to describe a person who seeks to own or operate a facility.

As explained on proposed, the Department has added this requirement because prior as well as existing experience owning or managing other facilities is a good indicator of a person's ability or inability to own a long-term care nursing facility. Having this information will allow the Department to investigate a prospective licensee's experience with owning or managing other facilities.

Paragraph (10)

The requirement proposed in paragraph (8) is moved to paragraph (10), on final-form, with amendment. On final-form, the Department replaces the words “person” with the words “prospective licensee” for consistency in the use of this term to describe a person who seeks to own or operate a facility. The Department adds “of 5% or more” after the word “interest” at the request of a commentator, and in response to IRRC's concern regarding the inconsistent use of the words “direct” and “indirect” interest.

As explained on proposed, the Department has added this requirement because the licensing and regulatory history of a prospective licensee's other long-term care nursing facilities demonstrates their ability to provide quality care to residents. A history of noncompliance or licensing issues, such as revocation of a license, demonstrates that there may be issues regarding the prospective licensee's ability to properly manage a facility or care for residents. Conversely,

no history of compliance issues is an indicator that the facilities owned or operated by the prospective licensee are well managed and provide quality care to residents.

Paragraph (11)

The requirement proposed in paragraph (9) is moved to paragraph (11), on final-form, with amendment. The Department proposed to require that the prospective licensee provide a detailed summary of current or settled civil actions or criminal actions filed against the person.

One commentator expressed concern that the word “current” is ambiguous and suggested adding a timeframe to this requirement while another commentator suggested adding the word “adjudicated.” The Department agrees that the word “current” is unclear and removes it. The Department adds the word “adjudicated” because the Department is only concerned about adjudicated and settled civil or criminal actions. The Department declines to put a timeframe on this requirement but will take the date of the legal action into consideration when conducting its analysis under § 201.12b (relating to evaluation of application for license of a new facility or change in ownership).

As explained on proposed, the Department has added this requirement because civil and criminal actions may not always be captured in a prospective licensee’s licensing and regulatory history. A wrongful death action, for example, may show that a prospective licensee acted inappropriately in providing care to a resident, but may not present itself from a regulatory perspective. Requiring a prospective licensee to provide this type of information provides an additional mechanism for capturing potential performance issues during the application process.

Paragraph (12)

The requirement proposed in paragraph (10) is moved to paragraph (12), on final-form, with amendment. The Department proposed that a prospective licensee provide information regarding any financial failures involving any persons identified in the application that resulted in a bankruptcy, receivership, assignment, debt consolidation or restructuring, mortgage foreclosure, corporate integrity agreement, or sale or closure of a long-term care nursing facility, the land it sits on or the building in which it is located.

A commentator asked for clarification regarding the term “financial failures.” The commentator pointed out that these types of actions may be taken by entities to remain viable and requested that consideration be given to the circumstances that necessitated the action and the way that an entity emerged from the action. In response to this comment, the Department replaces “financial failures involving persons identified in the application” with “a list of any persons, identified in paragraph (1), who have experienced financial distress” that resulted in a bankruptcy, receivership, assignment, debt consolidation or restructuring, mortgage foreclosure, corporate integrity agreement, or sale or closure of a long-term care nursing facility, the land it sits on or the building in which it is located. The Department will take into consideration the date and circumstances surrounding these types of actions when conducting its analysis under § 201.12b.

As explained on proposed, the Department has added this requirement because, to provide quality care, a facility must have the financial stability to properly operate. Staff must be paid, and residents must be provided the appropriate therapies, medications, and

accommodations for a facility to properly operate and provide quality care to residents. By obtaining information regarding a prospective licensee's financial health, the Department will be able to evaluate the ability of the prospective owner to properly operate a long-term care nursing facility.

Paragraph (13)

Based on comments received from public commentators, the Department adds a new paragraph to provide further transparency of a facility's organizational structure and relationships. Under paragraph (13), a prospective licensee is required to identify whether an immediate family relationship exists between a prospective licensee, a person identified under paragraph (1) (regarding ownership and ownership interest) and a person under paragraph (7) (regarding parent companies, stakeholders and related parties).

Paragraph (14)

The requirement proposed in paragraph (11) is moved to paragraph (14), on final-form, without amendment. One commentator asked that the Department amend this paragraph to require that the information sought be reasonably related to the finance and operation of facilities or other human service endeavors. Another commentator expressed concern that this paragraph is too vague and has the potential to delay approval of an application for a change in ownership. This commentator asked for examples of the types of information the Department may request. Another commentator requested that the Department amend this paragraph to include information responsive to inquiries from public comment on the application for license of a new facility or change in ownership.

After careful consideration, the Department declines to make these amendments. As explained on proposed, the purpose of this catch-all provision is to provide the Department with flexibility to require additional application information as circumstances warrant. The Department simply cannot predict every circumstance in which additional information is needed, or what information may be needed based on its review of the information submitted under subsection (b). However, this additional information is limited to the same type of class of information under paragraphs (1) through (12) under the Rules of Statutory Construction. 1 Pa.Code § 1.7 (relating to Statutory Construction Act of 1972 applicable).

Subsection (c)

In response to comments received from commentators and IRRC, the Department adds language in subsection (c) on final-form, to define the term "related party" used in subsection (b). This definition is added to provide clarity regarding the use of this term in subsections (b)(7) and (b)(8)(ii). Under this definition, a "related party" is a person that provides a service, facility or supply to a long-term care nursing facility or that is under common ownership or control, as defined in 42 CFR 413.17(b) (relating to cost to related organizations), and includes home offices; management organizations; owners of real estate; entities that provide staffing, therapy, pharmaceutical, marketing, administrative management, consulting, insurance or similar services; providers of supplies and equipment; financial advisors and consultants; banking and financial entities; any and all parent companies, holding companies, and sister organizations. The Department researched statutes and regulations from other states and considered the definition of "related party" from the Financial Accounting Standards Board (FASB), but

ultimately decided on this definition because the definition is tailored to services, facilities or supplies to the nursing facility and is less technical than that of the FASB definition, resulting in it being easier for the regulated community, residents, and others to understand.

Due to this addition, the language that was proposed in subsection (c) is moved to subsection (c), as described below.

Subsection (d)

The Department adds language in subsection (d), on final-form, to define the term “immediate family member” which is used under paragraph (13), as previously discussed. This definition is added to provide clarity regarding the use of this term. The Department has adopted the definition of “immediate family member” proposed by commentators. An “immediate family member” includes a spouse, biological parent, biological child, sibling, adopted child, adoptive parent, stepparent, stepchild, stepsibling, father-in-law, mother-in-law, sister-in-law, brother-in-law, son-in-law, daughter-in-law, grandparent, or grandchild.

Due to this addition, the language that was proposed in subsection (d) is moved to subsection (f), as described below.

Subsection (e)

As mentioned previously, the language in proposed subsection (c) is moved to subsection (e) on final-form, with amendments. The Department replaces the words “person seeking to operate or assume ownership” with the term “prospective licensee” for consistency in the use of this term to describe a person who seeks to own or operate a facility. As explained on proposed, the Department is including in this subsection additional requirements to be included with the application to aid the Department in its evaluation of a person's ability to operate a long-term care nursing facility. The amendments to subsection (b) focus on requirements that will allow the Department to assess the financial health and stability of a prospective licensee, as well as a prospective licensee’s history in operating long-term care nursing facilities. The proposed requirements in subsection (e), on the other hand, are intended to provide the Department with additional information, detailed as follows, regarding the prospective licensee’s intentions with respect to the actual operation of the long-term care nursing facility, to ensure that the prospective licensee will be able to provide safe and adequate care for long-term care nursing residents.

Paragraphs (1) through (5)

Paragraphs (1) and (2) are unchanged from proposed to final-form. As explained on proposed, the Department, in paragraph (1), is requiring that a prospective licensee provide a proposed staffing and hiring plan, which shall include management and oversight staff and the participants of the governing body. The Department in paragraph (2) is requiring that a prospective licensee provide a proposed training plan for staff.

Paragraph (3) is also unchanged from proposed to final-form. As explained on proposed, the Department is requiring, under paragraph (3), that a prospective licensee provide a proposed emergency preparedness plan that meets the requirements of 42 CFR 483.73(a) (relating to emergency preparedness). A commentator requested that the Department amend paragraph (3) to require a “proposed emergency, pandemic and disaster preparedness plan” to align with the

suggestion of commentators that the Department add requirements for pandemic and disaster preparedness plans. As explained later in this preamble, the Department has, after careful consideration, decided not to add requirements specifically for pandemic and disaster preparedness plans. Therefore, amending paragraph (3) to require submission of such plans would not be appropriate.

Paragraph (4) is amended from proposed to final-form. The Department proposed, in paragraph (4), to require that a prospective licensee provide the Department with proposed standard admissions and discharge agreements. A commentator asked the Department to clarify what is meant by a “discharge” agreement and whether this should instead be “transfer” agreement. IRRC also requested that the Department clarify what is meant by “discharge agreements.” The Department agrees that “discharge agreements” is incorrect and, in response to these comments, deletes the words “and discharge” before the word “agreement.” This provision as amended applies to proposed standard admissions agreements.

Paragraph (5) is amended from proposed to final-form. The Department proposed, in paragraph (5), to require that a prospective licensee provide a detailed budget for 3 years of operations, prepared in accordance with GAAP and to provide evidence of access to sufficient capital needed to operate the facility in accordance with the budget and facility assessment. As explained on proposed, having this information will allow the Department to assess the reasonableness of a prospective licensee’s proposed plans and the prospective licensee’s level of preparedness to operate a long-term care nursing facility. The Department, on final-form, replaces the words “generally accepted accounting principles” with the acronym “GAAP” to align with the use of this acronym in subsection (b). The Department also adds, at the request of a commentator, a cross-reference to the Federal requirements for a facility assessment under 42 CFR 483.70(c).

A commentator asked that the Department be more specific about what information should be included in the plans and budget required in paragraphs (1) through (5). This commentator stated that prospective licensees should be required to make clear how they will, for example, train and recruit staff, and they should be held accountable if they end up failing to carry out their Department-approved plans. As explained on proposed, the Department’s intent in requiring this staffing, hiring and training plan information is to assess the reasonableness of a prospective licensee’s plans and to assess the prospective licensee’s level of preparedness to operate a long-term care nursing facility. The Department, however, declines to add an additional requirement to this subsection holding a prospective licensee accountable if they fail to follow through with the initial plans that are submitted to the Department. The plans required under subsection (c) can and should evolve over time as the needs of the facility and residents change. In addition, the Department surveys for compliance with the requirements of the act and this subpart. Once an application for a license is approved by the Department, the licensee is expected and required to continue to meet the training and preparedness requirements of the act and this subpart. Facilities will be held accountable if they fail to do so.

Subsection (f)

The language in proposed subsection (d) is moved to subsection (f) on final-form with amendments. As explained on proposed, the Department recognizes that the application process that will now be required under this section is more comprehensive and detailed, with the

potential for applicants to miss something while adjusting to these new requirements. In addition, the Department may need additional information or explanations regarding information submitted with the application. The Department adds subsection (f) to provide a prospective licensee 30 days from the date of the denial of an application to cure defects in an application.

A commentator requested that the Department amend this subsection to permit a prospective licensee only one opportunity to cure a defective application. The Department agrees and makes this amendment on final-form. The Department, however, will work with prospective licensees to identify information that is missing before issuing a denial. As pointed out by the commentator, a need for repeated, continual submissions suggests that a prospective licensee may not have the ability to successfully operate a facility. Limiting a prospective licensee's ability to cure the application to one time will also ensure that prospective licensees take the application for licensure process seriously. The Department, on final-form, also replaces the word "person" with the term "prospective licensee" for consistency in the use of this term to describe a person who seeks to own or operate a facility.

Other comments

A commentator recommended that the Department add a new section outlining a prospective licensee's ability to appeal if an application for license of a new facility or change in ownership is denied. IRRC asked if there is a process for appeal of a denial of an application for license of a new facility or change in ownership. Existing § 201.15(c) (relating to restrictions on license) provides for an appeal of a final order or determination by the Department to the Health Policy Board. For additional clarity, on final-form, the Department has moved this subsection into its own section, at § 201.15b (relating to appeals) for ease of readability.

A commentator recommended that the Department add a new section to address disclosure and confidentiality of information and records, to indicate that an application for licensure is subject to disclosure under the Right-to-Know Law (RTKL), except for certain information, which would be considered confidential. After careful consideration, the Department declines to add this language due to the intent to be transparent regarding identification of ownership structure and staffing, hiring, training and emergency preparedness planning. The Department will address any need for redactions or confidentiality concerns through programmatic guidance,).

§ 201.12a. Notice and opportunity to comment

The language that was proposed in § 201.12a is moved to § 201.12b on final-form.

Commentators strongly recommended that the Department include a notice and public comment period for applications for new licenses and changes in ownership. Commentators stressed the need for transparency and accountability and public comment and feedback. Commentators recommended that prospective licensees be required to provide notice to the Office of the State Long-Term Care Ombudsman and the Office of the Local Long-Term Care Ombudsman. Commentators recommended that in the case of a change in ownership, prospective licensees also provide notice to residents and employees of the facility. Commentators suggested that this notice be provided directly to these individuals and published in a local newspaper, the *Pennsylvania Bulletin* or on the Department's website. Commentators strongly supported having a public comment period following the notice, as well, although one

commentator stressed that it is important that the inclusion of a public comment period not further delay the review process for applications for licensure.

IRRC asked what the process is for receiving public feedback and input on an application for licensure, and whether the Department should require that notification of a sale or change in ownership be provided to residents, their families, employees of the facility, and the public, as well as when should such notice be provided. IRRC asked the Department to explain how the public health, safety, and welfare of residents will be protected without a public notice and comment period. IRRC asked the Department to explain the reasonableness of not soliciting feedback from persons who may have direct knowledge of a prospective licensee's history of administration of a long-term care nursing facility.

In response to commentators and IRRC, new language is added to § 201.12a, on final-form, to provide for a notice and comment period, as described below.

Subsection (a)

Under subsection (a), a prospective licensee of a new facility is required to provide, in addition to the requirements in § 201.12 (relating to application for license of a new facility or change in ownership), concurrent written notice to the Office of the State Long-Term Care Ombudsman. The Department has included only that entity, under subsection (a), because in the case of a brand-new facility, there will not be any residents or employees yet to notify of the application for licensure.

Subsection (b)

Under subsection (b), a prospective licensee for a change in ownership is required to provide, in addition to the requirements in § 201.12, concurrent written notice to the residents of the facility being purchased or acquired and their resident representatives, employees of the facility being purchased or acquired, and the Office of the State Long-Term Care Ombudsman. The Department agrees with commentators that it is important for residents, resident representatives, and employees of the facility to be notified of a change in ownership.

In order to provide additional transparency and timely notice as requested by commentators, the Department added in subsection (d) a provision that the Department will post notice of the receipt of the applications for licensure and copies of completed application forms on the Department's website.

Subsection (c)

Subsection (c) sets forth the requirements for the contents of the notice. The notice shall contain the name and address of the facility, the name and address of the prospective licensee, the contact information for the State Long-Term Care Ombudsman, and a statement that an application for licensure has been submitted to the Department and that more information regarding the application, including the ability to comment, may be found on the Department's website. The Department added the requirement that the notice contain contact information for the State Long-Term Care Ombudsman, at the request of that office. The Department added the requirement for the notice to contain a statement that more information regarding the application for licensure, including the ability to comment, may be found on the Department's website so

that those directly impacted by the application for new licensure or change in ownership are notified of their ability to comment.

Subsection (d)

The Department will, in accordance with subsection (d), post notice of the receipt of an application for license of a new facility or change in ownership, and a copy of the completed application form submitted under § 201.12 on the Department's website and provide a 10-day public comment period. A stakeholder expressed concern, at the meeting on August 17, 2022, that 10 days is not enough time for the public to determine whether prospective licensees are bad actors and provide the Department with input. The Department chose a 10-day public comment period to align with the Department's current practice of providing a 10-day public comment period for requests for exceptions that are filed with the Department. Further, as mentioned previously, in balancing competing interests, the Department strives to complete its review of applications for new license or change in ownership in a timely manner, and does not want to delay the process by extending the timeline for review any further, out of concern for the health, safety, and welfare of residents, who particularly in the case of a change in ownership, need a timely and smooth transition whenever a facility is sold.

During the stakeholder meeting on August 17, 2022, a stakeholder also asked for clarification regarding the timeline, and asked specifically how long in advance of a sale of a facility does notice need to be provided to those individuals identified in subsections (a) and (b). As noted previously, under § 51.4, a facility must notify the Department at least 30 days prior to a change in ownership. Therefore, in the case of a change in ownership, the prospective licensee must submit the application form, fee and other items required under § 201.12 at least 30 days prior to the change. Under § 201.12a(b), the prospective licensee will be required to provide concurrent notice to residents, resident representatives, employees of the facility and the Office of the State Long-Term Care Ombudsman at the same time the application for new license or change in ownership is submitted to the Department. Under § 201.12a(d), the Department will post the application form on its website upon receipt and will provide a 10-day public comment period. The Department will conduct its review of all items submitted under § 201.12, as well as comments received during the 10-day public comment period, concurrently. As noted previously, the Department strives to conduct its review of applications for licensure efficiently and in a timely fashion, to ensure the health, safety, and welfare of residents.

§ 201.12b. Evaluation of application for license of a new facility or change in ownership

The language that was proposed in § 201.12a is moved to § 201.12b on final-form, with amendments, described below. As explained on proposed, the Department outlines in this section its process for the evaluation of an application for licensure of a new facility or change in ownership. The purpose of delineating, in regulation, the Department's role in the application process is to provide transparency and guidance to prospective licensees as to what the Department will be considering in its evaluation of applications.

Subsection (a)

Subsection (a) is amended from proposed to final-form to indicate that the Department will consider comments submitted under § 201.12a(d) (relating to notice and opportunity to comment) in addition to the application form and documents submitted under § 201.12. This

amendment is made on final-form, based on feedback from commentators and IRRC, which is described more fully in § 201.12a, above.

Subsection (b)

Subsection (b) is amended from proposed to final-form. The Department proposed to add language in subsection (b) indicating that it will approve or deny an application upon completion of the evaluation conducted under subsection (a). Senator Collett supports the addition of language requiring review of past performance related to owning or operating a facility in the Commonwealth or other jurisdictions. She further suggested that the Department consider putting together a publicly available report outlining the Department's approval or rejection of applications, including any underlying concerns and additional oversight requirements as a condition for licensure, if warranted. IRRC asked if the Department would produce such a report. In response to these comments, and in balancing the need for timely information, the Department adds on final-form, that it will post notice of the approval or denial of the application on its website. Posting this information on the Department's website will promote transparency by allowing the public to see whether an application for licensure has been approved or denied. Although the Department appreciates the comment regarding a departmental report in conjunction with an approval or denial of an application, the Department is not moving forward with this suggestion at this time due to concerns regarding delay in issuance of an approval or denial as a result of concurrently producing a detailed report.

Subsection (c)

Subsection (c) is amended from proposed to final-form. As explained on proposed, the Department outlines in this subsection what it will consider in determining whether to approve or deny an application. Specifically, the Department will consider the prospective licensee's past performance related to owning or operating a facility in this Commonwealth or other jurisdictions, the prospective licensee's demonstrated financial and organizational capacity and capability to successfully perform the requirements of operating a facility, and the prospective licensee's demonstrated history and experience with regulatory compliance, as evaluated in part by evidence of consistent performance in delivering quality care. Past performance and financial issues and a history of regulatory citations are all indications that an applicant may not be able to operate a long-term care nursing facility. On final-form, the Department replaces the word "person" with "prospective licensee" to align with the use of that term throughout the regulation to describe a person who seeks to own or operate a facility. The Department also adds on final-form, that it will consider comments submitted under § 201.12a(d), in response to feedback from commentators and IRRC, which is described more fully in § 201.12a, above.

Other comments

Several commentators requested that the Department add criteria that will result in the automatic denial of an application. IRRC asked if the Department has such criteria that could be placed in the regulation. In response, the Department does not have such criteria and declines to establish such criteria in regulation. The regulations provide that the Department will consider certain factors in determining whether to approve or deny an application. The Department will not base its decision on any one factor alone, but instead will consider all the factors delineated in § 201.12b(c). Further, it would be problematic to include a specific approach of weighing

these factors. Each application and the information submitted with it is different, and the Department cannot envision every type of scenario that may present itself during the application review process. The Department supports that a case-by-case approach is best.

A commentator and IRRC also asked what happens if an application for license of a new facility or change in ownership is in process on the effective date of the regulation. As noted elsewhere in this preamble, the effective date for § 201.12 will be October 31, 2023. Applications for licensure received prior to the effective date of the regulation, October 31, 2023, will be processed under the old requirements. Applications for licensure received on or after October 31, 2023, will be processed under the new requirements.

A commentator expressed support for the need to vet applications for licensure more diligently, particularly for a change in ownership, but asked that the Department also focus on steps to limit the number of facilities changing ownership by establishing reasonable and attainable regulatory requirements and addressing the chronic underfunding of facilities that rely on Medical Assistance (MA) reimbursement. Although it is unclear from this comment what the commentator means by establishing reasonable and attainable regulatory requirements, the Department has added robust requirements for applications for new facilities and changes in ownership. As part of this regulatory framework, the Department has provided in regulation the minimum standards required to ensure the health, safety, and welfare of residents. Additionally, the Department does not have the statutory oversight or authority with respect to MA funding. However, as provided in further detail in final-form Rulemaking 1 – *General Applicability and Definitions* and Rulemaking 4 – *Qualifications, Training, Job Duties, Recordkeeping, Program Standards, and Resident Rights and Services*, there was a substantial increase in funding for nursing facilities, including new nursing facility funding and increased MA payments beginning January 2023 (Act 2022-54; Act 2022-1A).

A commentator recommended that the process the Department plans to use to review applications be made publicly available to providers. As provided previously, section 201.12b publicly contains the factors that the Department will consider in determining whether to approve or deny an application. Specifically, the Department will consider the applicant's past performance related to owning or operating a facility in this Commonwealth or other jurisdictions, the applicant's demonstrated financial and organizational capacity and capability to successfully perform the requirements of operating a facility, the applicant's demonstrated history and experience with regulatory compliance, and the review of public comments the Department receives. After the review of an application and the consideration of these factors, the Department will either approve or deny an application. The Department's review will be on a case-by-case basis. The Department will then post notice of the approval or denial of the application on the Department's website. In addition, as stated previously, a prospective licensee will be permitted one opportunity under § 201.12(f) in which to cure an application, if needed.

A commentator indicated that it is imperative that the Department's new financial unit be fully staffed and trained, and that processes for the unit be in place prior to the effective date of the regulation to ensure timely review of applications, and to not force a facility undergoing a change in ownership to close due to a delay. The Department agrees that additional resources may be needed to review the new comprehensive and robust requirements for applications of new facilities and changes in ownership under this final-form rulemaking. As such, the Department will be pursuing additional funding for a financial unit to implement these new

provisions. Further, the effective date for §§ 201.12, 201.12a(c)(4) and (d), 201.12b, 201.13c(b) and (c) will be October 31, 2023 to ensure the Department can hire and train the new financial unit. This change also addresses comments and concerns received from commentators and IRRC about the proposed immediate effective date.

§ 201.13. Issuance of license for a new facility or change in ownership

As noted on proposed, the Department adds "for a new facility or change in ownership" to the title of this section to describe the contents of this section more accurately.

A commentator sought clarification as to whether the license issued under subsection (b) would be a regular license. A commentator suggested adding language that "admissions may begin under a new or changed ownership license" after a "regular license has been issued." This commentator also suggested adding that a regular license has a one-year term and must be renewed annually. Commentators also requested that the Department retain subsection (f), pertaining to provisional licenses. Commentators requested that the Department add language to indicate that a provisional license will be granted to a licensee of a new facility or change in ownership as a first or initial license. Another commentator indicated that prospective licensees for a change in ownership should be issued a provisional license if there are noncompliance issues that existed prior to the change in ownership.

IRRC asked if the license issued will be a regular license without conditions or if the license could be a provisional license. IRRC asked that, if the license can be a provisional license, that the Department clarify this and include a reference to section 812 of the act (35 P.S. § 448.812). IRRC also noted that the length of time that a license can be valid is not addressed and asked the Department to clarify this by including a timeframe in the regulation or a reference to section 809(a) of the act (35 P.S. § 448.809(a)).

In response to these comments, the Department notes that the license that is issued upon approval for a new facility or change in ownership could be either a regular license or a provisional license. Based on the comments received, the Department, on final-form, has added two new sections, § 201.13a (relating to regular license) and § 201.13b (relating to provisional license) to clarify the distinctions of when a regular license will be issued versus a provisional license. The Department has also included requirements and timelines for the renewal of a license in new § 201.13c (relating to license renewal). These new sections are described in more detail below.

Subsection (a)

Subsection (a) remains deleted on final-form. As noted previously, the Department moved the first sentence of this subsection into § 201.12(a.1) with amendments. The second sentence of this subsection, regarding the non-transferability of a license, is duplicative of section 809(a)(3) of the act (35 P.S. § 809(a)(3)), which provides that no license shall be transferable except upon written approval of the Department. As explained on proposed, the Department uses the change of ownership process as the mechanism for taking a license from one entity and providing the opportunity for another entity to be issued a license, assuming approval. To obtain approval from the Department, the new, prospective licensee is required, under existing regulation, to apply for a license. To eliminate confusion, the Department has updated § 201.12 and added new requirements under § 201.12a to clarify the specific

requirements for prospective licensees of new facilities and those who desire to assume ownership of an already existing facility.

Subsection (b)

Subsection (b) is amended from proposed to final-form. The Department, on final-form, amends the citation to §§ 201.12 and 201.12a to “this part” to account for the inclusion of new requirements for notice and comment, and the renumbering of § 201.12a to § 201.12b to accommodate these requirements. The remainder of this subsection remains unchanged from proposed to final-form. As explained on proposed, the Department deletes language in this subsection referring to the application form and the licensure fee as requirements for the application form and fee are addressed in the act and in § 201.12. The Department also deletes language requiring an inspection. As explained on proposed, the Department conducts inspections of new facilities, but may or may not conduct a survey when there is a change in ownership. A commentator suggested adding “and that issuance of a license is appropriate” before the word “met” and “under” §§ 201.12—201.12b. After carefully considering this comment, the Department declines to make this change as the purpose of this part is to codify the regulatory requirements for licensure and adding “appropriateness” language does not add substantively to the regulation.

Commentators expressed concern over the Department’s deletion of language requiring an inspection under this subsection. Commentators requested that the Department add language to the regulation to indicate that licensees of both new facilities and changes in ownership are subject to a survey within the first 3-6 months of operation. Commentators argued that new licensees need to be subject to higher scrutiny, and surveys are necessary to confirm substantial compliance with requirements that could not be measured before the licensee was operating the facility. IRRC suggested that the Department consider including such a survey into regulation. IRRC stated, “If such an inspection is not implemented in the final-form regulation, we ask the Department to explain how it will ensure protection of the public health, safety and welfare without heightened oversight in the initial months of operation.”

After careful consideration and balancing the frequency of existing surveys, the Department declines to add this amendment. Existing surveys and unannounced examinations ensure protection of the public health, safety and welfare. For new facilities, the Department conducts an occupancy survey before a facility opens, a survey after the facility opens, and a survey for certification once the facility has a few residents. The Department also conducts surveys of all facilities on an annual basis. Further, the Department conducts a survey of a facility when a complaint is received, including subsequent unannounced examinations. Lastly, to the extent any deficiencies were previously identified by a prior owner of a facility, a new owner is required to correct these deficiencies to retain a facility license.

Subsection (c)

Subsection (c) remains deleted on final-form. As explained on proposed, the Department is deleting the existing language in subsection (c), which delineates the fees to be submitted with an application for licensure of a long-term care nursing facility because section 807(b) of the act (35 P.S. § 448.807) sets forth the fees that are to accompany an application for a license or

renewal of a license. Because these fees are set by statute, the Department is not able to change them, and it is not necessary to specify the fees in regulation.

Commentators indicated they do not object to the deletion of this subsection. However, they feel that applicants need clear information on what is required in the application process and feel it is not readily apparent that fee information is available elsewhere. After careful consideration, the Department declines to retain subsection (c) in response to these comments. Section 201.12(b) explicitly provides that a prospective licensee is to submit a completed application and the fee required under section 807 of the act (35 P.S. § 448.807). The Department has appropriately cross-referenced these requirements in subsection (b) and does not see a need to repeat them. Further, the same commentators commented on the need for the General Assembly to increase the fees set forth in the act. The Department agrees and would support such an amendment to the act. Providing a cross-reference to the act, rather than delineating the fees, ensures that there will be no conflict between the regulations and the act when these required fees are updated by legislation.

Subsection (d)

Subsection (d) is unchanged from proposed to final-form. As explained on proposed, the Department adds "the name and address of the owner of the facility" to the license that will be issued to the owner of a facility. Including this information on a facility's license will increase transparency for residents and their families, by allowing them to quickly determine who the owner of the facility is and how to contact them. The Department deletes "and types" of beds from the license as well because this requirement is obsolete. The Department no longer classifies bed types, and thus, this information is not needed on the license.

Subsection (e)

The Department deletes subsection (e) on final-form and as mentioned previously, adds § 201.13a to delineate the requirements for the issuance of a regular license, in response to public comment.

Subsection (f)

Subsection (f) remains deleted on final-form. The Department had proposed to delete subsection (f) to eliminate duplication and potential confusion between the regulations and section 812 of the act (35 P.S. § 448.812). As mentioned previously, the Department adds § 201.13b, on final-form, to delineate the requirements for the issuance of a provisional license in response to public comment.

Subsection (g)

Subsection (g) remains deleted on final-form. As explained on proposed, the Department has moved subsection (g) into § 201.14 (relating to responsibility of licensee) so that this language clearly applies to licenses for new facilities or changes in ownership. Long-term care nursing facilities are required to have on file the most recent inspection reports. Moving this language to § 201.14 clarifies that this responsibility applies to all facilities.

Subsection (h)

Subsection (h) remains deleted on final-form. As explained on proposed, the Department deletes the language in existing subsection (h), pertaining to plans of correction, because it is duplicative of the requirements in the act and not necessary to have in the regulations. Under section 814(a) of the act (35 P.S. § 448.814(a)), the Department shall provide notice when, upon inspection, investigation, or complaint, it finds a violation of its regulations or the act. This notice shall require the facility to act or submit a plan of correction. The Department currently uses an electronic system for the submission of the plan of correction and provides facilities with instructions on how to submit a plan of correction through this system when one is required.

Commentators requested that the Department add language outlining the enforcement steps available to the Department. Commentators indicated that while enforcement actions are covered in multiple sections of the act, it would be beneficial to spell them out in regulation for the regulated community, residents, and others. Commentators also argued that spelling the enforcement actions out in regulation sends a message that the Department takes compliance with the act and its regulations seriously. In response to these comments and after careful consideration, the Department adds § 201.15a (relating to enforcement), on final-form to consolidate the information, as described below.

Subsection (i)

Subsection (i) remains deleted on final-form. As explained on proposed, the Department deletes subsection (i) to eliminate duplication and potential confusion and conflict between the regulations and the requirements in the act. Section 809(b) of the act (35 P.S. § 809(b)) provides that a license shall be posted in a conspicuous place on the premises, at all times.

§ 201.13a. Regular license

On final-form, the language in proposed § 201.13a is moved to § 201.13c to accommodate the addition of this new section, which delineates the requirements for a regular license. As explained previously, this section is added on final-form, in response to feedback from commentators and IRRC, who requested that the Department clarify the circumstances under which a regular license will be issued, as well as the length of time for which a license is valid.

Under this section, the Department will issue a regular one-year license when the facility is in full compliance with section 808 of the act (35 P.S. § 448.808) and is in full or substantial compliance with the provisions of this subpart. This language aligns with the requirements of the act in sections 808 and 809 (35 P.S. § 448.809). In addition, to provide further clarity, the Department added definitions for “full compliance” and “substantial compliance” in § 201.3 (relating to definitions) in final-form Rulemaking 1 – *General Applicability and Definitions*.

§ 201.13b. Provisional license

As explained previously, this section is added on final-form, in response to feedback from commentators and IRRC, who asked that the Department not delete § 20.13(f)(relating to issuance of license for a new facility or change in ownership) and that the Department clarify the circumstances under which a provisional license will be issued, as well as the length of time for which a license is valid.

Subsection (a)

Subsection (a) provides the circumstances in which the Department will issue a provisional license. The Department will issue a provisional license when there are numerous deficiencies or a serious specific deficiency, the facility is not in substantial compliance with this subpart and the Department finds that: (1) the facility is taking appropriate steps to correct the deficiencies in accordance with a timetable submitted by the facility and agreed upon by the Department; and (2) there is no cyclical pattern of deficiencies over a period of 2 or more years. This language is copied directly from existing § 201.13(f)(1).

Subsection (b)

Subsection (b) provides that a provisional license will be issued for a specified time period of no more than 6 months. This is copied from the first sentence of existing § 201.13(f)(2).

Subsection (c)

Subsection (c) provides that a regular license will be issued, upon substantial compliance, including the payment of any fines and fees. This is copied from the last sentence of existing § 201.13(f)(2). The Department adds “including the payment of any fines and fees” to align with sections 807 and 812 of the act (35 P.S. §§ 448.807 and 448.812).

§ 201.13c. License renewal

As mentioned previously, the language from proposed § 201.13a is moved into this section on final-form, with amendments, as explained below.

Subsection (a)

This subsection is unchanged from proposed to final-form. As explained on proposed, this subsection requires long-term care nursing facilities to apply for renewal of their licenses on a form prescribed by the Department with the fee required by the act. This is already required of facilities seeking to renew their licenses, and thus, does not impose any new obligation on facilities.

Subsection (b)

The language in subsection (b) is new on final-form. The Department adds to subsection (b), a requirement for facilities to submit an updated annual financial report that meets the requirements set forth in § 201.12(b)(8). After careful consideration for the need for additional transparency, this language is added in response to commentators who requested that facilities submit an annual financial report, as explained in § 201.12(b)(8) above. Adding this submission requirement for a financial report at the same time as the license renewal process will make it easier and efficient for the regulated community to know when to submit this information. It will also be efficient and pertinent for the Department to review this information at the same time as it reviews the application for license renewal.

Subsection (c)

Subsection (c) is new on final-form. Under subsection (c), a facility is required to file the application to renew its license, and the updated financial report, at least 21 days before the

expiration of the current license, unless the Department directs otherwise. This subsection is added in response to commentators and IRRC requesting that the Department spell out in regulation the timeline for renewal of a license. The Department generally sends out the application for renewal approximately 90 days before the license is due to expire. Requiring the application and updated financial report to be submitted at least 21 days in advance provides the Department with the time needed to review the application and the updated financial report. However, because the Department can envision circumstances in which additional time is needed, the Department adds “unless otherwise directed by the Department” to permit a facility additional time when circumstances warrant. This addition also aligns with the addition of language to § 201.15(b)(1) (relating to restrictions on license), at the request of commentators, to prevent the expiration of a license where the term expires due to a Departmental delay, a National emergency or State disaster emergency.

Subsection (d)

Subsection (d) is new on final-form. Subsection (d) provides that the Department will renew a regular one-year license under this section if the facility is in full compliance with section 808 of the act (35 P.S. § 448.808) and is in full or substantial compliance with the provisions of this subpart. This language is added, in response to public comments and IRRC’s comments, to further clarify the circumstances under which a regular license will be renewed, as well as the length of time for which a license is valid.

Subsection (e)

Subsection (e) provides that a provisional license may be renewed no more than three times at the discretion of the Department. This is copied from the second sentence of existing § 201.13(f)(2). The Department further adds a cross-reference to section 812 of the act (35 P.S. § 448.812) and § 201.13b (relating to provisional license) for additional clarity.

§ 201.14. Responsibility of licensee

Subsection (a)

Subsection (a) is amended from proposed to final-form. As explained on proposed, the Department adds the word “Federal” in the first sentence and adds the following sentence, “This includes complying with all applicable Federal and State laws, and rules, regulations and orders issued by Federal, State or local agencies.” On final-form, the Department adds “the Department and other” before the word “Federal” to align with subsection (b), below. The purpose of this addition is to make it clear that licensees are required to adhere to all applicable Federal and State laws, and rules, regulations and orders issued by the Department and Federal, State, and local agencies. This clarification is important because there may be instances, such as during the COVID-19 pandemic, where information is rapidly changing, and it is imperative that facilities are adhering to rules, regulations and orders that are being issued to ensure the health and safety of residents.

Subsection (b)

Subsection (b) is unchanged from proposed to final-form. As explained on proposed, the Department removes the word “the” from this subsection for grammatical reasons. The Department replaces the word “insuring” with “ensuring” for the correct usage and spelling of

that word. The Department replaces the phrase, "this subpart, and other relevant Commonwealth regulations" with the phrase, "all applicable Federal and State laws, and rules, regulations, and orders issued by the Department and other Federal, State and local agencies." The Department makes this amendment to clarify that a licensee is responsible for ensuring that all services for the administration or management of the facility are compliant with all applicable Federal and State laws, and rules, regulations and orders issued by the Department and other Federal, State and local agencies. As mentioned previously, this clarification is important in situations, such as a pandemic, where information is rapidly changing and adherence to rules, regulations and orders is imperative to ensure the health and safety of residents.

Subsection (c)

Subsection (c) is amended from proposed to final-form. As explained on proposed, the Department adds "within 24 hours" from subsection (c) to this subsection to require a licensee, through the administrator, to report to the appropriate Division of Nursing Care Facilities field office within 24 hours serious incidents, involving residents, that are outlined in § 51.3 (relating to notification). The Department moves this language from subsection (c) into subsection (c) and deletes subsection (c) to streamline this requirement and for ease of readability. The Department also moves the phrase "as set forth in § 51.3 (relating to notification)" into the first sentence, for grammatical reasons. On final-form, the Department adds "as soon as possible, or, at the latest" before the words "within 24 hours" to align more closely with the current language in subsection (c), that is being deleted.

A commentator requested that the Department amend this subsection to require a licensee to timely comply with all reporting requirements related to hospitalizations or critical incidents as required by MA and other payor sources, including section 1150B of the Social Security Act (42 U.S.C.A. § 1320b-25), and to comply with all applicable reporting requirements outlined in the Older Adult Protective Services Act (OAPSA) (35 P.S. §§ 10225.101 - 10225.5102), the Adult Protective Services Act (35 P.S. §§ 10210.101 – 10210.704), and the Child Protective Services Law (CPSL) (23 Pa.C.S. §§ 6301 – 6388). After careful consideration, the Department declines to make this amendment to limit compliance to only these specific citations. Under § 201.14(a), a facility is required to comply with all applicable Federal and State laws, and rules, regulations and orders issued by the Department and other Federal, State or local agencies.

Subsection (d)

Subsection (d) remains deleted from proposed to final-form. As explained on proposed, the Department deletes this subsection because it is duplicative of requirements that are already outlined in § 51.3 (relating to notification). Health care facilities, including long-term care nursing facilities, are required to comply with the existing requirements in § 51.3.

In contrast, commentators requested that the Department re-enumerate State reporting requirements in this subsection to include requiring facilities to report events that cause or result in a resident's death or present an immediate danger of death or serious harm; events that cause or result in serious injury or significant change in a resident's condition; when staffing levels in the facility are below State minimum requirements; and deaths or serious injuries due to neglect, as defined in 42 CFR 483.5 (relating to definitions). Although the Department agrees with the reporting of these events, the Department declines to add this amendment since they are already

required under existing Department regulations. Under § 51.3(c), which applies to all healthcare facilities, a facility is required to report noncompliance with any of the Department's regulations, where noncompliance seriously compromises quality assurance or patient safety. Further, under § 51.3(f), a facility is also required to report situations or occurrences of events at the facility which could seriously compromise quality assurance or patient safety. Section 51.3(g) provides a list of types of events that seriously compromise quality assurance or patient safety, which includes, but is not limited to, death or serious injury. This list is not all-inclusive. As provided under this existing regulation, any event that seriously compromises quality assurance or patient safety requires notification as a reportable event. This includes the reduction in staffing levels below the minimum requirements because a reduction in minimum staffing health and safety requirements seriously compromises quality assurance and resident safety.

Subsection (e)

This subsection remains deleted on final-form. As explained on proposed, the Department deletes this subsection due to the amendments to subsection (c), described above.

Subsection (f)

This subsection is amended from proposed to final-form. The Department did not propose any amendments to this subsection. A commentator, however, recommended adding the Office of the Local Long-Term Care Ombudsman and the Office of the State Long-Term Care Ombudsman to the requirement that a facility notify the Department upon receipt of a strike notice. After careful consideration of this comment and discussion with the Office of the State Long-Term Care Ombudsman, the Department agrees with notification to the State Long-Term Care Ombudsman upon receipt of a strike notice and adds this requirement on final-form.

Subsection (g)

This subsection is unchanged from proposed to final-form. The Department did not propose any amendments to this subsection.

Subsection (h)

This subsection is amended from proposed to final-form. As explained on proposed, the Department deletes "and" before "program" and adds "and any other" before the word "information" in this subsection. The Department deletes the word "as" between the words "information" and "the" for grammatical reasons. The addition of "and any other" before "information" provides the Department with flexibility to require licensees to provide other information that may be important to ensure the health and safety of residents. The Department adds this language due to lessons learned during the COVID-19 pandemic. Throughout the COVID-19 pandemic, there have been times when the Department needed information such as the number of COVID cases within facilities, vaccination status and patient per day calculations. Adding this language into the regulation will make it easier to obtain this information from facilities. The Department deletes ", on forms issued by the Department," to allow for flexibility in how this information is obtained by the Department. Having this flexibility has proven to be vital during the COVID-19 pandemic.

A commentator expressed concern that the addition of "and any other" information is very vague and open-ended. The commentator recommended that, at a minimum, the

Department add language to ensure that facilities are provided advance notice of any additional reporting requirements. IRRC asked that the Department amend the final-form regulation to ensure that facilities are provided advance notice of any additional reporting requirements. After careful consideration, the Department agrees with this suggestion. The Department will provide advance notice for new reporting requirements unless there is an emergency. For example, as the Department experienced with the COVID-19 pandemic, there may be ad-hoc needs for specific data or emergent needs that the Department and facilities may need to address immediately. Based on the comments received, the subsection is amended to require facilities to report to the Department census, rate, program occupancy and any other information. The Department will provide advance notice of new reporting requirements, except in instances of an emergency.

Subsection (i)

This subsection is unchanged from proposed to final-form. As explained previously, the Department moves the language from § 201.13(g) to this subsection. The Department adds the word "Federal" to the requirement that a facility have on file the most recent inspection reports. As explained on proposed, the Department adds the word "Federal" because facilities that participate in Medicare or MA are subject to surveys for compliance with the Federal requirements. A commentator expressed support for requiring facilities to keep inspection reports on file and providing them to parties who request to see them. The commentator noted that this increases transparency and helps consumers and their families to make better informed decisions when looking for a facility, especially those who may not have internet access to review information on CMS' website.

Subsection (j)

This subsection is unchanged from proposed to final-form. Under this subsection, long-term care nursing facilities are required to conduct facility assessments that meet the requirements of 42 CFR 483.70(e), as necessary, but at least quarterly. Currently, under the Federal requirements, a facility must conduct and document a facility-wide assessment to determine the resources necessary to care for its residents competently during both day-to-day operations and emergencies. The facility must review and update the assessment, as necessary, and at least annually.

The Department explained, on proposed, that quarterly assessments provide a more accurate mechanism through which a facility can determine the resources, particularly staffing levels, needed to properly care for residents. Throughout the year, a facility may experience changes in resident population, resident conditions and staff levels and competencies. Updating the facility assessment on at least a quarterly basis will allow a facility to properly and accurately assess the needs of residents and ensure that residents are receiving the most appropriate care and services.

Some commentators expressed support for the Department's proposal to require quarterly facility assessments, with one commentator in proposed Rulemaking 1 suggesting that the Department increase facility assessments to a monthly basis. These commentators pointed out that the facility assessment is a valuable tool for evaluating resident acuity, ensuring adequate staffing, and meeting the needs of the facility's specific resident population. These

commentators pointed out that resident populations, and their needs, change with some frequency so the value of performing a quarterly assessment is enormous. Commentators pointed out, as well, that performing a meaningful facility assessment on a quarterly basis will improve internal quality assurance and will identify areas of noncompliance. These commentators further stated that the assertion that this is simply a burdensome paperwork requirement misses the importance of this requirement.

Other commentators, however, disagreed with the Department's proposal, indicating that they feel that the requirement for quarterly assessments is excessive, will create an undue burden on facilities that are already desperate to hire additional staff, and will burden staff and facilities with additional documentation and review, which will not contribute to an increase in quality of care. IRRC asked that the Department explain the need for this provision and how the benefits of this new requirement for quarterly facility-wide assessments outweigh the economic impacts.

After careful consideration and examination of the competing interests between consumer advocates and industry stakeholders, the Department declines to reduce the proposed requirement and will still require that a facility conduct facility-wide assessments at least quarterly to ensure resident health and safety. Requiring facilities to conduct a quarterly assessment provides timely indication of any systemic problems at the facility and identifies key areas for improvement. Currently, long-term care nursing facilities are required to conduct and document a facility-wide assessment at least annually to determine what resources are necessary to care for its residents during both day-to-day operations and emergencies. Analyzing the resident population every quarter provides a snapshot as to the overall conditions of the residents at that time, including the most common diseases, conditions, and diagnoses during that time period, and if the facility has the appropriate staff and/or equipment to take care of those residents, particularly if a trend, such as prevalence of pressure ulcers, is found among those residents. Further, staffing levels and job description openings also change on an ongoing basis. Quarterly facility assessments identify and document those changes, while providing a quality assurance function to assure that resident needs are being met by staff and financed.

§ 201.15. Restrictions on license

Subsection (a)

This subsection remains deleted on final-form. A commentator recommended keeping subsection (a) with the addition of the words "in whole or in part" after the word "transferrable." The commentator did not provide an explanation for this recommendation, and the Department declines to make this amendment. As explained on proposed, the Department deletes subsection (a) as it is duplicative of sections 809(a)(3) and (4) of the act (35 P.S. §§ 448.809). Section 809(a)(3) provides that a license shall not be transferable except upon prior written approval of the Department. Section 809(a)(4) of the act, provides that a license shall be issued only for the health care facility or facilities named in the application. The Department uses the current change of ownership process as the mechanism for taking a license from one entity and providing the opportunity for another entity to be issued a license, assuming approval. Changes in ownership are addressed in §§ 201.12—201.13, as discussed previously.

Subsection (b)

This subsection is amended from proposed to final-form.

As explained on proposed, the Department adds the word “automatically” before the word “void” to reflect the understanding, in practice, that a long-term care nursing facility’s license becomes automatically void, without notice, if any of the conditions in paragraphs (1) through (4) occur.

Paragraph (1) of subsection (b) is amended from proposed to final-form to add, at the request of a commentator, “unless the term expires due to a departmental delay, a national or state emergency or natural or human-caused disaster.” The Department agrees that the addition of this language would be beneficial to the regulated community because there was a lot of confusion surrounding expired licenses during the COVID-19 pandemic. As explained on proposed, in paragraph (1), the Department also replaces the phrases “expiration date has been reached” with the phrase “license term expires” to eliminate possible confusion by clarifying that a license becomes automatically void when the license term expires.

Also, as explained on proposed, in paragraph (3), the Department deletes “for the transfer of the license” to eliminate confusion in terminology because the Department uses the change of ownership process as the mechanism for taking a license from one entity and giving it to another. No amendments are made to paragraphs (2) and (4).

Subsection (c)

This subsection is deleted on final-form. A commentator recommended that the Department add a new section outlining a prospective licensee’s ability to appeal if an application for license of a new facility or change in ownership is denied. IRRC asked if there is a process for appeal of a denial of an application for license of a new facility or change in ownership. Existing § 201.15(c) (relating to restrictions on license) provides for an appeal of a final order or determination by the Department to the Health Policy Board. On final-form, the Department has moved this subsection into its own section, at § 201.15b (relating to appeals), for clarity and ease of readability.

§ 201.15a. Enforcement

This section is added on final-form, in response to public comment, and delineates the types of actions the Department may take to enforce compliance with the act and this subpart. Specifically, actions the Department may take to enforce include, but are not limited to, requiring a plan of correction, issuing a provisional license, revoking a license, appointing a temporary manager, limiting or suspending admissions to a facility, and assessing fines or civil monetary penalties. Commentators requested that the Department add this language, which outlines the enforcement steps available to the Department. Commentators indicated that while enforcement actions are covered in multiple sections of the act, it would be beneficial to spell them out in regulation for the regulated community, residents, and others. Commentators also argued that spelling the enforcement actions out in regulation sends a message that the Department takes compliance with the act and its regulations seriously. The Department agrees that including enforcement actions in the regulation will be helpful for the regulated community, residents, employees and others.

A commentator requested that the Department also add language indicating that facilities will be cited for violations of both State and Federal requirements. The Department declines to make this amendment, as this could result in confusion for facilities that do not participate in Medicare or MA. Facilities that do not participate in Medicare or MA are not required, under Federal law, to comply with the Federal requirements, and thus, can only be cited for failure to comply with those requirements under State law by virtue of the amendment to § 201.2 in final-form Rulemaking 1— *General Applicability and Definitions*.

§ 201.15b. *Appeals*

As noted previously, this section is added on final-form in response to public comments. The language in existing § 201.15(c) is copied into this section, without amendment, to make it easier for the regulated community and others to find.

§ 201.17. *Location*

This section is amended from proposed to final-form. The Department proposed to delete the existing language in this section and replace it with the following:

With the approval of the Department, a facility may be located in a building that also offers other health-related services, such as personal care, home health, or hospice services, and may share services such as laundry, pharmacy and meal preparations. The facility shall be operated as a unit distinct from other health-related services.

Commentators asked that this language be clarified because it is not clear whether the co-located health-related services would be offered as separate services under the facility's license or whether there would be separately licensed providers providing other health-related services co-located at the same physical location as the facility. A commentator suggested adding "within which there are separately licensed providers that operate and provide" between the words "building" and "other health-related." The Department agrees that this suggested language makes this provision clearer and adds it on final-form. As revised on final-form, the provision provides: "With the approval of the Department, a facility may be located in a building with other providers and share services as follows: (1) The provider is licensed, as applicable; (2) The provider operates or provides other health related services, such as personal care, home health or hospice services; (3) The shared services may include services such as laundry, pharmacy and meal preparations; (4) The facility shall be operated as a unit distinct from other health-related services."

As explained on proposed, the Department has had to grant a large number of exceptions to permit long-term care nursing facilities to be located in a building that offers other health-related services, such as personal care. The Department recognizes that it is beneficial for long-term care nursing facilities and their residents to have these types of services within the same building. The Department also recognizes that it is beneficial for these entities to share centralized services, such as laundry and meal preparations, to reduce costs. The amendment to § 201.17 accommodates these circumstances. The Department will, however, continue to consider the facility as a distinct unit and prohibit the facility from mixing approved beds, residents, and staff between the related health care services.

§ 201.22. *Prevention, control and surveillance of tuberculosis (TB)*

Subsection (a)

Subsection (a) is unchanged from proposed to final-form. As explained on proposed, the Department is only making one amendment to this subsection. The Department replaces the word "employees" with "employees" to reflect the current usage and spelling of that term.

Subsection (b)

Subsection (b) is unchanged from proposed to final-form. As explained on proposed, the Department adds "screening, testing and surveillance for TB" to clarify that this section applies to the screening, testing and surveillance of TB as well as the treatment and management of TB. The Federal requirements for long-term care nursing facilities in 42 CFR Part 483, Subpart B do not specifically address TB. The Department determined that it is important to keep this subsection to clarify that facilities must follow the Centers for Disease Control and Prevention (CDC) guidelines related to TB screening, testing and surveillance. *See TB Screening and Testing of Health Care Personnel. (2021)*. Retrieved from <https://www.cdc.gov/tb/topic/testing/healthcareworkers.htm>. The CDC provides the most current and updated guidance regarding TB. The Department is proposing to add "and Prevention" after the words "Centers for Disease Control" as the appropriate name for the CDC is the Centers for Disease Control and Prevention.

Subsections (c) through (n)

Subsection (c) through (n) remain deleted on final-form. As explained on proposed, the Department deletes subsections (c) through (n) as they are outdated requirements. As noted previously, the CDC provides the most updated guidance for facilities to follow regarding TB.

§ 209.1. *Fire department service*

This section remains deleted on final-form. As explained on proposed, the Department deletes this section as it is outdated and covered by the Department's adoption of the Federal requirements in § 201.2 (relating to requirements), in final-form Rulemaking 1– *General Applicability and Definitions*. The Federal requirements include requirements for smoke alarms and sprinkler systems, and also incorporate by reference the National Fire Protection Association's *Life Safety Code* (NFPA 101). *See* 42 CFR 483.90. The *Life Safety Code* includes requirements for fire protection and the safety of residents, including fire department service. All facilities are already required to comply with the *Life Safety Code* under existing § 203.1 (relating to application of the *Life Safety Code*) and will continue to be required to comply with the *Life Safety Code* by virtue of the Department's expanded incorporation of the Federal requirements in § 201.2 in final-form Rulemaking 1. This assumes approval of final-form Rulemaking 1.

§ 209.7. *Disaster preparedness*

This section remains deleted on final-form. As explained on proposed, the Department deletes this section as it is outdated and covered by the Department's adoption of the Federal requirements in § 201.2, which are addressed in final-form Rulemaking 1– *General Applicability and Definitions*. Emergency preparedness, which encompasses disaster preparedness, is

thoroughly covered in 42 CFR 483.73. Facilities are required to have an emergency plan, which must include strategies to assess risks identified in an all-hazards, community-based risk assessment. All-hazards include emerging infectious diseases, as well as natural or man-made emergencies, which may include care-related emergencies, equipment and power failures, interruptions in communications (including cyberattacks), loss of all or a portion of a facility, and interruptions in the normal supply of essentials such as food and water.

Commentators requested that the Department retain and expand this section to include emergencies, disasters, and pandemics. Commentators requested that the Department require that facilities have a written plan to address each of these types of occurrences that is submitted with the application for licensure and annually thereafter for approval by the Department. Commentators also requested that the Department require that the plan include various items, such as the plan for communication with residents and families, the plan for communication with State and local public health and emergency management agencies, and how the facility will ensure sufficient supplies and staff, in addition to other requirements. After careful consideration, the Department declines to make this amendment. As mentioned, the requirements for an emergency plan are in 42 CFR 483.73 and encompass the items that the commentators would have the Department add to regulation. The Federal requirements are broad in that the emergency plan is based on facility-based and community-based risk assessments. Emergency plans therefore will differ from facility-to-facility. For example, a facility along the Susquehanna River would likely need to include emergency plans for flooding, but another facility that is built in a higher elevated, remote location that is not at risk of flooding would not need to include such plans. Instead, that facility may need to include a plan for loss of power and emergency fuel due to their remote location.

All facilities that participate in Medicare or MA are already required to meet 42 CFR 483.73. Although private-pay facilities are currently required to have disaster plans, the additional requirements for emergency planning will be a new requirement for the private-pay facilities. This requirement also assumes approval of final-form Rulemaking 1 - *General Applicability and Definitions*, which incorporates this requirement by reference in § 201.2.

In response to commentators who requested that the Department require that the emergency plan be submitted with the application for licensure and annually thereafter for approval by the Department, the Department notes that under § 201.12(e)(3), prospective licensees will be required to submit a proposed emergency preparedness plan as part of the application for licensure. In addition, the Department conducts annual surveys for compliance with the requirements of the act and its regulations. By virtue of the expanded incorporation of the Federal requirements in § 201.2, the Department will be surveying for compliance with this requirement under State law. This assumes approval of final-form Rulemaking 1 - *General Applicability and Definitions*.

§ 209.8. Fire drills

This section remains deleted on final-form. The Department deletes this section as it is outdated and covered by the Federal requirements. Requirements for fire drills are addressed in the *Life Safety Code*, which is incorporated by reference in the Federal requirements. See 42

CFR 483.90. All facilities are already required to comply with the *Life Safety Code* under existing § 203.1 (relating to application of the *Life Safety Code*) and will continue to be required to comply with the *Life Safety Code* by virtue of the Department's expanded incorporation of the Federal requirements in § 201.2 in final-form Rulemaking 1— *General Applicability and Definitions*. This assumes approval of final-form Rulemaking 1.

Commentators requested that the Department keep and expand this section to include all types of safety drills, including drills for emergencies, disasters, pandemics and active shooters, and to rename the section to reflect this change. After careful consideration, the Department declines to make this amendment. Under 42 CFR 483.73, facilities are required to develop and maintain an emergency preparedness programs, training and testing. These plans are required to be based on facility-based, community-based risk assessment, utilizing an all-hazards approach, that include a process for cooperation and collaboration with local, State and Federal emergency preparedness officials to maintain an integrated response during a disaster or emergency. 42 CFR 483.73(a)(1) and (4). Further, these plans require policies and procedures that address safe evacuation and a means to shelter in place for residents, staff and volunteer, in addition to communication plans. 42 CFR 483.73(b)(3) and (4) and (c). Initial and annual training is required for emergency preparedness. 42 CFR 483.73(d)(1). Further, drills are covered under 42 CFR 483.73(d)(2), which requires facilities to “conduct exercises to test the emergency plan at least twice per year, including unannounced staff drills.”

All facilities that participate in Medicare or MA are already required to meet 42 CFR 483.73. Although private-pay facilities are currently required to have both disaster plans and fire drill requirements, the additional requirements for emergency planning will be a new requirement for the private-pay facilities. This requirement also assumes approval of final-form Rulemaking 1 – *General Applicability and Definitions*, which incorporates this requirement by reference in § 201.2.

§ 211.1. Reportable diseases

This section is unchanged from proposed to final-form. As explained on proposed, based on the recommendations of the LTC Work Group, and due to a rise in bed bug infestations, the Department adds "bed bug infestations" to the reporting requirements of subsection (b). A commentator expressed support for this addition.

Commentators requested that the Department add a new subsection to clarify that facilities must report pandemic-prone infectious diseases, such as COVID-19, and other State or Federally declared pandemics or infectious disease outbreaks, to the Department and other relevant agencies, in the manner, frequency and format required by the Department. Commentators also recommended that the Department create a new section to address any future pandemic-related illnesses or outbreaks, where the facility would be required to follow all currently applicable State and Federal regulations, guidance, and protocols. Commentators recommended the Department add language for requirements of an infection control plan that would specifically address pandemics. After careful consideration, the Department declines to make this amendment. As provided previously, under § 201.14 (relating to responsibility of licensee) (as revised in this final-form rulemaking), a facility is required to comply with all applicable Federal and State laws, rules, regulations and orders. This would include any laws, rules, regulations and orders related to pandemic-related illnesses or outbreaks. Further, existing

§ 27.3 (relating to reporting outbreaks and unusual diseases, infections and conditions) authorizes the Department to designate any unusual or group expression of illness as a public health emergency, which includes pandemic-related illnesses and outbreaks. Similarly, § 27.4 (relating to reporting of cases) and Subchapter B (relating to reporting of diseases, infections and conditions) of Chapter 27 (relating to communicable and noncommunicable diseases) address the frequency and format of reportable diseases.

Comments on Effective Date

Commentators and IRRC commented regarding the Department's proposal to set the same effective date, upon publication, for all four final-form rulemakings. IRRC asked the Department to address these concerns and explain why this timeframe was reasonable.

In response to commentators and IRRC, the final-form regulations for all four regulatory packages will take effect on July 1, 2023, with the following exceptions. In this final-form rulemaking, sections 201.12a(a), (b), and (c)(1) through (3), which require prospective licensees to provide written notice to certain individuals, shall take effect on February 1, 2023. Sections 201.12, 201.12b, 201.13c(b) and (c), and 201.12a(c)(4) and (d) shall take effect on October 31, 2023. In final-form Rulemaking 4, section 211.12(f.1)(3) and (i)(2) shall take effect on July 1, 2024. This will allow the regulated community a reasonable amount of time to adequately plan and initiate the staffing and budget changes necessary to achieve compliance.

Fiscal Impact and Paperwork Requirements

Fiscal Impact

In response to the comments and concerns raised during the September 15, 2021 Senate Health and Human Services and Aging and Youth Committees joint legislative hearing, throughout the public comment process, and in other discussions, the Governor's Fiscal Year 22-23 budget proposal proposed a MA rate increase of \$190 million; \$91 million in state funding to be matched with \$99 million in federal funds for the first 6 months of calendar year 2023 and a proposed \$250 million one-time investment of American Rescue Plan Act (ARPA) funds in long-term living programs, including direct one-time funding for all facilities to support their workforce and help them to hire more staff to meet the requirements of the forthcoming regulations. The funding was proposed to be provided to facilities in advance of the expected staffing increases to allow facilities to stabilize their existing workforce and recruit additional staff prior to the regulatory increases going into effect.

Following the Governor's budget proposal, industry stakeholders called for \$294 million in MA funding in the Commonwealth's FY 22-23 budget. The FY 22-23 Appropriations Act signed by Governor Wolf included bipartisan support for a historic increase in one-time and ongoing funding for facilities. As enacted, \$147 million in state funding was appropriated to support implementation of the Department's regulations. Specifically, this funding will be used to support a 17.5% Medicaid rate increase beginning January 1, 2023, which allows facilities time to ramp up staffing to meet the direct care staffing hours required on July 1, 2023. Assuming Federal approval, these state funds will be matched with an additional \$159 million in federal funds, totaling \$306 million in Medicaid funding for the first 6 months of calendar year

2023. All nursing facilities will also receive \$131 million in one-time ARPA funding during FY 22-23. A detailed fiscal impact for the regulated community, the commonwealth and local government is as follows:

Regulated community

The amendments will apply to all 682 long-term care nursing facilities licensed by the Department. These facilities provide health services to more than 72,000 residents. This total includes nineteen county-owned and operated facilities, six veterans' homes that are operated by DMVA, 654 privately-owned facilities that participate in Medicare or MA, and three private-pay facilities that do not participate in Medicare or MA. The requirement for facility assessments to be performed, at least, on a quarterly basis is a new requirement. Currently, facilities are required to complete facility assessments at least annually; however, practice varies regarding frequency. Since facilities are already required to care for their residents, determine and plan for staffing, resources and operate their facilities, the conducting and documenting of a facility assessment is a standard business practice with a nominal fiscal impact due to the increase in required frequency. As provided previously, quarterly assessments are used to determine what resources are needed to care for residents during both day-to-day operations and emergencies. Further, these assessments provide a timely indication of any systemic problems at a facility and assist with identifying areas for improvement.

There is also a nominal fiscal impact anticipated with the submission of financial reports and the additional submission of contact information for related parties, parent companies and shareholders. Facilities will incur a nominal cost related to the submission of the annual financial report with the renewal of the application for licensure under § 201.13c (relating to license renewal). This will initially be a new requirement for all facilities effective October 31, 2023, followed by an annual update. Facilities should already have, in their possession, the documents required for the submission of the annual financial report, as these items are already produced in the regular course of business. However, facilities may incur a nominal cost for copying these documents for submission to the Department.

Prospective licensees

Prospective licensees will incur nominal costs related to the submission of additional documents with the application for licensure in § 201.12 (relating to application for license of a new facility or change in ownership). Prospective licensees should already have, in their possession, the financial documents and other information listed in § 201.12, as many of these documents are already produced in the regular course of business. However, prospective licensees may incur nominal costs for copying these documents for submission to the Department. Prospective licensees will need to spend time compiling this information for submission to the Department, as well. The Department anticipates that a prospective licensee will need to spend approximately an hour compiling this information for submission. Prospective licensees will need to expend time developing other items required under § 201.12, such as a staffing plan and an emergency preparedness plan. The Department anticipates that a prospective licensee may need to spend approximately 2 to 4 hours developing these items.

Prospective licensees will also incur nominal costs, such as postage and the cost of paper and supplies, associated with providing the notice under § 201.12a (relating to notice and opportunity to comment) to the Office of the State Long-Term Care Ombudsman and residents, resident representatives, and employees, if applicable. The Department anticipates that a prospective licensee may need to expend anywhere from a few minutes to an hour, depending on the number of notices required under this section. Prospective licensees may incur additional costs if they choose to consult with an accountant or an attorney when completing these paperwork requirements.

Commonwealth – Department

The Department's surveyors perform the function of surveying and inspecting long-term care nursing facilities for compliance with both Federal and State regulations. The elimination of subsections that are outdated and duplicative of the Federal requirements will streamline the survey process for long-term care nursing facilities and provide consistency and congruency to the stakeholder industry. This, in turn, will reduce confusion in the application of the standards that apply to long-term care nursing facilities. These streamlining provisions will not increase costs to the Department. However, the Department is anticipating an approximate cost of \$600,000 to hire accountants to establish a financial unit to review and manage the new financial submissions from facilities. This estimate includes an estimated annual cost of \$590,312 for salaries and benefits and initial operating costs of \$9,250 for equipment and office space.

The Department also estimates that there will be a cost to update licenses to add the additional information under § 201.13 (relating to issuance of license for new facility or change in ownership) and to update the computer system for the creation of internal reporting for review of new information. It is estimated that the Department will need to expend approximately \$55,000 for these updates, which includes the cost for a vendor assessment.

Commonwealth – DMVA

Of the 682 long-term care nursing facilities licensed by the Department, six facilities are veterans' homes that are operated by DMVA. These facilities are already required to comply with the Federal requirements and thus, are already required to comply with existing Federal requirements.

The DMVA-operated licensed facilities will not incur any additional cost due to aligning with the Federal requirements. As noted, these facilities are already required to comply with the Federal requirements. Although there is additional paperwork requirements associated with quarterly facility assessments, the department considers this to be a standard business practice with a nominal fiscal impact due to the increase in required frequency.

Commonwealth – Department of Human Services

Although the provisions of this final-form rulemaking, which relate to ownership, management and health and safety, will not have a cost impact to the Department of Human Services, a substantial increase in funding for nursing facilities, including new nursing facility funding and increased Medical Assistance payments beginning January 2023, was enacted under Act 2022-54 and appropriated under the General Appropriations Act of 2022 (Act 2022-1A).

Local Government

As mentioned previously, there are currently 19 county-owned long-term care nursing facilities, licensed by the Department. These facilities account for approximately 7.5% (6,524 beds) of licensed nursing facility beds across the Commonwealth. Allegheny County owns four of the nursing homes; the remaining homes are in the following 15 counties: Berks, Bradford, Bucks, Chester, Clinton, Crawford, Delaware, Erie, Indiana, Lehigh, Monroe, Northampton, Philadelphia, Warren and Westmoreland.

All county-owned long-term care nursing facilities participate in Medicare or MA and thus, are already required to comply with the Federal requirements.

The county-owned licensed facilities will not incur any additional cost due to align with the Federal requirements. As noted, these facilities participate in Medicare or MA and thus, already required to comply with the Federal requirements. Similar to other facilities, these facilities already have to conduct facility assessments. Although there are additional paperwork requirements associated with quarterly facility assessments, the Department considers this to be a standard business practice with a nominal fiscal impact due to the increase in required frequency.

Residents of Long-Term Care Nursing Facilities

Approximately 72,000 individuals that reside in the 682 long-term care nursing facilities licensed by the Department will be affected by the amendments. Residents will be positively impacted by the increased frequency in facility assessments. As provided previously, quarterly assessments are used to determine what resources are needed to care for residents during both day-to-day operations and emergencies. Further, these assessments provide a timely indication of any systemic problems at a facility and assist with identifying areas for improvement. Specifically, analyzing the resident population every quarter provides a snapshot as to the overall conditions of the residents at that time, including the most common diseases, conditions, and diagnoses during that time period, and if the facility has the appropriate staff and/or equipment to take care of those residents, particularly if a trend is found among those residents.

Paperwork Requirements

The Department's adoption of quarterly facility assessments will result in additional paperwork requirements for facilities. There are also additional paperwork requirements related to the submission of financial reports and the submission of contact information for related parties, parent companies and shareholders. These submissions are required upon application and annually.

Small Business Analysis

IRRC commented that the Department did not identify and provide an estimate of the number of small businesses that will be impacted by the regulation. IRRC asked if the Department, in conjunction with other agencies, can evaluate potential impacts on small businesses.

Under section 3 of the Regulatory Review Act, 71 P.S. § 745.3, a small business is “defined in accordance with the size standards described by the United States Small Business Administration’s Small Business Size Regulations under 13 CFR Ch. 1 Part 121 (relating to Small Business Size Regulations) or its successor regulation.” Under 13 CFR 121.101 (relating to what are SBA size standards), the Small Business Administration’s (SBA) “size standards determine whether a business entity is small.” Size standards are developed under the North America Industry Classification System (NAICS). The Department applied the NAICS standards to determine how many long-term care nursing facilities, licensed by the Department, are small businesses.

The Department conducted a search on the NAICS website to find the NAICS code for long-term care nursing facilities. The NAICS code for nursing care facilities (skilled nursing facilities) is 623110. The Department looked this code up in the table located at 13 CFR 121.201 (relating to what size standards has SBA identified by NAICS codes) and determined that a long-term care nursing facility is a small business if it has \$30 million or less in annual receipts. The Department then pulled the latest long-term care nursing facility cost report from CMS to determine the impact to facilities that participate in Medicare or MA. The latest cost report data from CMS is 2018. Data.CMS.gov. Skilled Nursing Facility Cost Report. Retrieved from <https://data.cms.gov/provider-compliance/cost-report/skilled-nursing-facility-cost-report/data>. The Department applied current Federal Standards of Accounting to this data to determine each facility’s annual receipts. Based on this analysis, the Department determined that 623 facilities that participate in Medicare or MA have \$30 million or less in annual receipts. Although the data from CMS is from 2018, the Department believes that currently, at least the same number of facilities, if not more, would meet the definition of a small business. This analysis aligns with the Department’s previous assumption that most long-term nursing facilities licensed by the Department meet the definition of a small businesses.

The Department also asked stakeholders during the meetings held in 2021 and 2022 for assistance in determining the impact to small businesses. The stakeholders were not able to provide the Department with specific information regarding how the Department’s proposed regulations would impact small businesses. However, during the stakeholder meeting for Rulemakings 1 and 2, a stakeholder suggested that the Department search GuideStar, which provides financial information regarding nonprofit entities, to determine whether the three private-pay facilities are small businesses. The Department searched the GuideStar website at <https://www.guidestar.org/> for the three private-pay facilities that are licensed by the Department. Based on this data, one of the private-pay facilities, Friends Home in Kennett/Linden Hall, meets the definition of a small business applying the NAICS standards. Another private-pay facility, Foulkeways at Gwynedd does not meet the definition of a small business based on its gross receipts. Data for the third private-pay facility, Dallastown Nursing Center, is not available on GuideStar, but for the purposes of this analysis, the Department assumes that Dallastown is a small business.

In sum, at least 91% of nursing facilities meet the definition of a small business. Consistent with the HCFA and function of licensure, the purpose of these regulatory amendments is to ensure the health, safety, and welfare of all residents of long-term care nursing

facilities in this Commonwealth by providing the minimum health and safety standards. Given that most facilities are a small business and the need for surveying for the health and safety of residents, the Department did not establish differing criteria for nursing facilities that are small business compared to the minority of facilities that are not small businesses. Further, in determining the minimum health and safety requirements, the department considered the myriad of received comments, feedback from meetings and stakeholder groups and attempted to balance the interests between consumers and the stakeholder industry. The Department's responsibility to ensure that residents receive safe, quality care applies to all residents of long-term care nursing facilities in this Commonwealth, and it is critical that all residents of long-term care nursing facilities receive the same level of high-quality care, regardless of whether the facility they reside in is a small business.

IRRC also asked that the Department work with the regulated community to calculate and address the economic impact of additional quarterly assessments on facilities, particularly those that are small businesses. Although the Department inquired regarding the economic impact during a June stakeholder meeting, no comments or responses were provided. As additional background, when facility assessments were first required through the Federal Department of Health and Human Services (DHHS), due to existing requirements for sufficient staffing for acuity needs, no fiscal impact or burden was anticipated. Specifically, DHHS provided:

“We are finalizing our requirement for facilities to conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. LTC facilities must already determine and plan for what staffing they will need, as well as the other resources that will be required to care for their residents and operate their facilities. Thus, we believe that conducting and documenting a facility assessment is a standard business practice and do not include a burden for this requirement in the impact analysis.”

81 FR 68688, 68844 (October 4, 2016)

In working with DMVA, who operates 6 long-term care facilities, it indicated that the cost of conducting a facility assessment is insignificant, as it just involves compiling information. DMVA does not anticipate an increase in costs or labor to meet the increased frequency of a currently utilized assessment. DMVA currently has quality assurance staff to perform this function.

Statutory Authority

Sections 601 and 803 of the HCFA (35 P.S. §§ 448.601 and 448.803) authorize the Department to promulgate, after consultation with the Health Policy Board, regulations necessary to carry out the purposes and provisions of the HCFA. Section 801.1 of the HCFA (35 P.S. § 448.801a) seeks to promote the public health and welfare through the establishment of regulations setting minimum standards for the operation of health care facilities that includes long-term care nursing facilities. The minimum standards are to assure safe, adequate, and efficient facilities and services and to promote the health, safety and adequate care of patients or residents of those facilities. In section 102 of the HCFA (35 P.S. § 448.102), the General

Assembly has found that a purpose of the HCFA is, among other things, to assure that citizens receive humane, courteous and dignified treatment. Finally, section 201(12) of the HCFA (35 P.S. § 448.201(12)) provides the Department with explicit authority to enforce its rules and regulations promulgated under the HCFA.

The Department also has the duty to protect the health of the people of this Commonwealth under section 2102(a) of the Administrative Code of 1929 (71 P.S. § 532(a)). The Department has general authority to promulgate regulations under section 2102(g) of the Administrative Code of 1929).

Effectiveness/Sunset Date

This final-form rulemaking will become effective on July 1, 2023, except as follows. The effective date for § 201.12a(a), (b) and (c)(1)-(3) will be February 1, 2023. The effective date for §§ 201.12, 201.12a(c)(4) and (d), 201.12b, 201.13c(b) and (c) will be October 31, 2023. A sunset date will not be imposed. The Department will monitor the regulations and update them as necessary.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on March 2, 2022, the Department submitted notice of this proposed rulemaking, published at 52 Pa.B. 1626 (March 19, 2022), to IRRC and the Chairpersons of the Senate Health and Human Services Committee and the House Health Committee for review and comment.

Under section 5(c) of the Regulatory Review Act, 71 P.S. § 745.5(c), IRRC, the Senate Health and Human Services Committee and the House Health Committee were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Department has considered all comments from IRRC, the Senate Health and Human Services Committee, the House Health Committee, and the public.

Under section 5.1(e) of the Regulatory Review Act, 71 P.S. § 745.5a(e), on _____, 2022, the final-form rulemaking was deemed approved by the Senate Health and Human Services Committee and the House Health Committee. Under section 5.1(e) of the Regulatory Review Act, IRRC met on _____, 2022 and approved the final-form rulemaking.

Contact Person

Additional information regarding this final-form rulemaking may be obtained by contacting Ann Chronister, Director, Bureau of Long-Term Care Programs, by phone at (717) 547-3131, by email at RA-DHLTCRegs@pa.gov or by mail at the following address: 625 Forster Street, Rm. 526, Health and Welfare Building, Harrisburg, PA 17120. Persons with a disability may submit questions in alternative format such as by audio tape, Braille, or by using V/TT (717) 783-6514 or the Pennsylvania Hamilton Relay Service at (800) 654-5984 (TT). Persons who require an alternative format of this document may contact Lori Gutierrez at the previous address or telephone number so that necessary arrangements can be made.

Findings

The Department finds that:

(1) Public notice of intention to adopt the regulations adopted by this order has been given under sections 201 and 202 of the Act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202), and the regulations promulgated under those sections at 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law and all comments were considered in drafting this final-form rulemaking.

(3) The amendments made to the final-form rulemaking do not enlarge the original purpose of the proposed rulemaking as published under section 201 of the Act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. § 1201).

(4) The adoption of the regulations is necessary and appropriate for the administration of the Health Care Facilities Act (35 P.S. §§ 448.101—448.904b).

Order

(1) The regulations of the Department at Title 28 of the Pennsylvania Code at §§ 201.12—201.17, 201.22, 209.1, 209.7, 209.8 and 211.1 are amended as set forth in Annex A.

(2) The Department shall submit this final-form regulation to the Office of Attorney General and the Office of General Counsel for approval as required by law.

(3) The Department shall submit this final-form regulation to IRRC, the Senate Health and Human Services Committee and the House Health Committee as required by law.

(4) The Department shall certify this final-form regulation, as approved for legality and form, and shall deposit it with the Legislative Reference Bureau as required by law.

(5) This final-form regulation shall take effect on July 1, 2023, except as follows. Section 201.12a(a), (b) and (c)(1)—(3) shall take effect February 1, 2023. Sections 201.12, 201.12a(c)(4) and (d), 201.12b, 201.13c(b) and (c) shall take effect October 31, 2023.

**LIST OF COMMENTATORS WHO REQUESTED MORE INFORMATION ON DEPARTMENT OF HEALTH
LONG-TERM CARE NURSING FACILITY REGULATION #s 10-221, 10-222, 10-223, 10-224¹**

Commentator Name	Commentator Address
Carol Dieffenbach	220 Main Street, Unit 2 Towanda, PA 18848-1822
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Jeffrey Long	685 Angela Drive Greensburg, PA 15601
John Cusick	Northampton County Government Center 669 Washington St. Easton, PA 18042
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¹ Due to the overlap in comments between regulatory packages, the Department has compiled the list of commentators who requested more information on the four final-form long-term care nursing facility regulations into one list and provided a copy of all four packages to these commentators.

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Annex A

TITLE 28. HEALTH AND SAFETY

PART IV. HEALTH FACILITIES

Subpart C. LONG-TERM CARE FACILITIES

CHAPTER 201. APPLICABILITY, DEFINITIONS, OWNERSHIP AND
GENERAL OPERATION OF LONG-TERM CARE NURSING FACILITIES.

OWNERSHIP AND MANAGEMENT

§ 201.12. Application for license of a new facility or change in ownership.

(a) [An application for a license to operate a facility shall be made under section 807 of the act (35 P.S. § 448.807). The application form shall be obtained from the Division of Nursing Care Facilities, Bureau of Quality Assurance, Department of Health.] (Reserved).

(a.1) A person may not operate or assume ownership of a facility without first obtaining a license from the Department.

(a.2) A person seeking to operate or assume ownership PROSPECTIVE LICENSEE of a facility shall obtain an application form from the Division of Nursing Care Facilities, Department of Health.

(b) [The following shall be submitted with the application for licensure] In addition to the completed application and fee required under section 807 of the act (35 P.S. § 448.807), a person seeking to operate or assume ownership PROSPECTIVE LICENSEE of a facility shall submit the following:

(1) [The names and addresses of a person who has direct or indirect ownership interest of 5% or more in the facility as well as a written list of the names and addresses of the facility's officers and members of the board of directors.] The names, addresses, e-mail addresses and phone numbers of any person who MEETS ANY OF THE FOLLOWING: has or will have an ownership or control interest in the facility, whether the interest is in its profits or in the land or building occupied and used as the facility, as well as a written list of the names, addresses, e-mail addresses and phone numbers of the facility's officers and members of the board of directors. For purposes of this subsection, a person who has or will have ownership or control interest is:

(i) A person with HAS OR WILL HAVE a direct or indirect ownership interest of 5% or more in the facility.

(ii) The organization that holds HOLDS OR WILL HOLD the license or OWNERSHIP INTEREST IN the land ON WHICH THE FACILITY IS LOCATED or THE building occupied and used as the facility IN WHICH THE FACILITY IS LOCATED.

(iii) OWNS OR WILL OWN A WHOLE OR PART INTEREST IN ANY MORTGAGE, DEED, TRUST, NOTE OR OTHER LONG-TERM LIABILITY SECURED IN WHOLE OR IN PART BY THE EQUIPMENT USED IN THE FACILITY, THE LAND ON WHICH THE FACILITY IS LOCATED OR THE BUILDING IN WHICH THE FACILITY IS LOCATED.

(2) If the [owner] A **person** IDENTIFIED IN PARAGRAPH (1) is a nonprofit corporation, a complete list of the [names and addresses] **names, addresses, e-mail addresses and phone numbers** of the officers and directors of the corporation and an exact copy of its charter and articles of incorporation which are on file with the Department of State as well as amendments or changes.

(3) If the [owner] A **person** IDENTIFIED IN PARAGRAPH (1) is a partnership, the [names and addresses] **names, addresses, e-mail addresses and phone numbers** of partners.

(4) The name, address, **e-mail address, phone number** and license number of the administrator.

(5) The names, addresses, e-mail addresses and phone numbers of any persons that have or will have a direct or indirect interest WHO HAVE OR WILL HAVE AN INTEREST **in the management of the facility or the provision of services at the facility.**

(6) The person's corporate history. THE NAMES, ADDRESSES, E-MAIL ADDRESSES AND PHONE NUMBERS OF THE FACILITY'S OFFICERS AND MEMBERS OF THE BOARD OF DIRECTORS.

(7) THE NAMES, ADDRESSES, E-MAIL ADDRESSES AND PHONE NUMBERS OF THE FOLLOWING:

(i) A PARENT COMPANY.

(ii) A SHAREHOLDER.

(iii) A RELATED PARTY OF THE PERSONS IDENTIFIED IN PARAGRAPHS (1) THROUGH (6).

(8) AN ANNUAL FINANCIAL REPORT WHICH SHALL INCLUDE THE FOLLOWING:

(i) AUDITED FINANCIAL STATEMENTS PREPARED IN ACCORDANCE WITH GENERALLY ACCEPTED ACCOUNTING PRINCIPLES (GAAP). IF GAAP REQUIRES CONSOLIDATED FINANCIAL STATEMENTS, THEN CONSOLIDATED STATEMENTS SHALL BE PROVIDED.

(ii) A VISUAL REPRESENTATION OF THE CURRENT OWNERSHIP STRUCTURE, WHICH SHALL INCLUDE PARENT COMPANIES, SHAREHOLDERS,

AND ANY RELATED PARTIES OF THE PERSONS IDENTIFIED IN PARAGRAPHS (1) THROUGH (6).

(iii) A SUPPLEMENTAL SCHEDULE OF ANNUAL GROSS REVENUES, PREPARED IN ACCORDANCE WITH GAAP. THE SUPPLEMENTAL SCHEDULE SHALL BE BROKEN OUT BY PAYOR TYPE.

~~(7)~~ (9) A list of every licensed LONG-TERM CARE NURSING facility in any state, the District of Columbia or territory in which the person PROSPECTIVE LICENSEE has or HAS had A DIRECT OR INDIRECT INTEREST OF 5% OR MORE any percentage of interest in the ownership, management or real property of that facility.

~~(8)~~ (10) The person's PROSPECTIVE LICENSEE'S licensing and regulatory history in all jurisdictions where the person PROSPECTIVE LICENSEE has or has had a direct or indirect ownership interest OF 5% OR MORE in a facility.

~~(9)~~ (11) A detailed summary of current ADJUDICATED or settled civil actions or criminal actions filed against the person PROSPECTIVE LICENSEE.

~~(10)~~ (12) Financial failures involving persons identified in the application A LIST OF ANY PERSONS, IDENTIFIED IN PARAGRAPH (1), WHO HAVE EXPERIENCED FINANCIAL DISTRESS that resulted in a bankruptcy, receivership, assignment, debt consolidation or restructuring, mortgage foreclosure, corporate integrity agreement, or sale or closure of a LONG-TERM CARE nursing facility, the land it sits on or the building in which it is located.

(13) IDENTIFICATION OF WHETHER AN IMMEDIATE FAMILY MEMBER RELATIONSHIP EXISTS BETWEEN A PROSPECTIVE LICENSEE, A PERSON UNDER PARAGRAPH (1) AND A PERSON UNDER PARAGRAPH (7).

~~(11)~~ (14) Any additional information the Department may require.

(c) FOR THE PURPOSES OF SUBSECTION (B), A "RELATED PARTY" IS A PERSON THAT PROVIDES A SERVICE, FACILITY OR SUPPLY TO A LONG-TERM CARE NURSING FACILITY OR THAT IS UNDER COMMON OWNERSHIP OR CONTROL, AS DEFINED IN 42 CFR 413.17(B) (RELATING TO COST TO RELATED ORGANIZATIONS). THE TERM INCLUDES THE FOLLOWING:

- (1) A HOME OFFICE.
- (2) A MANAGEMENT ORGANIZATION.
- (3) AN OWNER OF REAL ESTATE.
- (4) AN ENTITY THAT PROVIDES STAFFING, THERAPY, PHARMACEUTICAL, MARKETING, ADMINISTRATIVE MANAGEMENT, CONSULTING, INSURANCE OR SIMILAR SERVICES.
- (5) A PROVIDER OF SUPPLIES AND EQUIPMENT.
- (6) A FINANCIAL ADVISOR OR CONSULTANT.

(7) A BANKING OR FINANCIAL ENTITY.

(8) A PARENT COMPANY, HOLDING COMPANY, OR SISTER ORGANIZATION.

(d) FOR THE PURPOSES OF SUBSECTION (B), AN "IMMEDIATE FAMILY MEMBER" INCLUDES A SPOUSE, BIOLOGICAL PARENT, BIOLOGICAL CHILD, SIBLING, ADOPTED CHILD, ADOPTIVE PARENT, STEPPARENT, STEPCHILD, STEPSIBLING, FATHER-IN-LAW, MOTHER-IN-LAW, SISTER-IN-LAW, BROTHER-IN-LAW, SON-IN-LAW, DAUGHTER-IN-LAW, GRANDPARENT OR GRANDCHILD.

(e) In addition to the information required under subsection (b), a person seeking to operate or assume ownership PROSPECTIVE LICENSEE of a facility shall provide the following:

(1) A proposed staffing and hiring plan, which shall include the management and oversight staff, the structure of the facility's governing body and its participants.

(2) A proposed training plan for staff.

(3) A proposed emergency preparedness plan that meets the requirements of 42 CFR 483.73(a) (relating to emergency preparedness).

(4) Proposed standard admissions and discharge agreements.

(5) A detailed budget for 3 years of operations, prepared in accordance with generally accepted accounting principles GAAP, and evidence of access to sufficient capital needed to operate the facility in accordance with the budget and the facility assessment CONDUCTED UNDER 42 CFR 483.70(e) (RELATING TO ADMINISTRATION).

(d) (f) A person PROSPECTIVE LICENSEE who fails, under this section, to demonstrate capacity to operate a facility, will be given 30 days from the date of the denial of an application to cure the application. A PROSPECTIVE LICENSEE WILL BE PERMITTED ONE OPPORTUNITY, UNDER THIS SUBSECTION, IN WHICH TO CURE THE APPLICATION.

§ 201.12a. NOTICE AND OPPORTUNITY TO COMMENT.

(a) IN ADDITION TO THE REQUIREMENTS IN § 201.12 (RELATING TO APPLICATION FOR LICENSE OF A NEW FACILITY OR CHANGE IN OWNERSHIP), A PROSPECTIVE LICENSEE OF A NEW FACILITY SHALL CONCURRENTLY PROVIDE WRITTEN NOTICE TO THE OFFICE OF THE STATE LONG-TERM CARE OMBUDSMAN WHEN THE PROSPECTIVE LICENSEE SUBMITS ITS APPLICATION.

(b) IN ADDITION TO THE REQUIREMENTS IN § 201.12, A PROSPECTIVE LICENSEE FOR A CHANGE IN OWNERSHIP OF A FACILITY SHALL CONCURRENTLY PROVIDE WRITTEN NOTICE TO THE FOLLOWING:

(1) RESIDENTS OF THE FACILITY BEING PURCHASED OR ACQUIRED, AND THEIR RESIDENT REPRESENTATIVES.

- (2) EMPLOYEES OF THE FACILITY BEING PURCHASED OR ACQUIRED.
 - (3) THE OFFICE OF THE STATE LONG-TERM CARE OMBUDSMAN.
- (c) THE WRITTEN NOTICE SHALL PROVIDE THE FOLLOWING INFORMATION:
- (1) THE NAME AND ADDRESS OF THE FACILITY.
 - (2) THE NAME AND ADDRESS OF THE PROSPECTIVE LICENSEE.
 - (3) THE CONTACT INFORMATION FOR THE STATE LONG-TERM CARE OMBUDSMAN.
 - (4) A STATEMENT THAT AN APPLICATION FOR LICENSURE HAS BEEN SUBMITTED TO THE DEPARTMENT AND MORE INFORMATION REGARDING THE APPLICATION, INCLUDING THE ABILITY TO COMMENT, MAY BE FOUND ON THE DEPARTMENT'S WEBSITE.
- (d) THE DEPARTMENT WILL POST NOTICE OF THE RECEIPT OF AN APPLICATION FOR LICENSE OF A NEW FACILITY OR CHANGE IN OWNERSHIP AND A COPY OF THE COMPLETED APPLICATION FORM SUBMITTED UNDER § 201.12 ON THE DEPARTMENT'S WEBSITE AND PROVIDE A 10-DAY PUBLIC COMMENT PERIOD.

§ 201.12b. Evaluation of application for license of a new facility or change in ownership.

(a) The Department will conduct an evaluation of the application, which will include consideration of the application form and documents submitted under § 201.12 (relating to application for license of a new facility or change in ownership) AND COMMENTS SUBMITTED UNDER § 201.12a(d) (RELATING TO NOTICE AND OPPORTUNITY TO COMMENT).

(b) Upon completion of the evaluation conducted under subsection (a), the Department will approve or deny the application AND POST NOTICE OF THE APPROVAL OR DENIAL OF THE APPLICATION ON THE DEPARTMENT'S WEBSITE.

(c) The Department will consider the following in determining whether to approve or deny an application:

(1) The person's PROSPECTIVE LICENSEE'S past performance related to owning or operating a facility in this Commonwealth or other jurisdictions.

(2) The person's PROSPECTIVE LICENSEE'S demonstrated financial and organizational capacity and capability to successfully perform the requirements of operating a facility based on the information provided under § 201.12.

(3) The person's PROSPECTIVE LICENSEE'S demonstrated history and experience with regulatory compliance, including evidence of consistent performance in delivering quality care.

(4) COMMENTS SUBMITTED UNDER § 201.12a(d).

§ 201.13. Issuance of license for a new facility or change in ownership.

(a) [A person may not maintain or operate a facility without first obtaining a license issued by the Department. A license to operate a facility is not transferable without prior approval of the Department.] **(Reserved).**

(b) A license to operate a facility will be issued when the Department [receives the completed application form and the licensure fee and when, after inspection by an authorized representative of the Department, it has been] **has** determined that the necessary requirements for licensure have been met **under §§ 201.12 (relating to application for license of a new facility or change in ownership) and § 201.12a (relating to evaluation of application for a new facility or change in ownership)** THIS PART.

(c) [The required fee for a license is:

Regular Licenses (new or renewal)	\$250
Each inpatient bed in excess of 75 beds	\$2
Provisional I License	\$400
Each inpatient bed	\$4
Provisional II License	\$600
Each inpatient bed	\$6
Provisional III License	\$800
Each inpatient bed	\$8
Provisional IV License	\$1,000
Each inpatient bed	\$10]

(Reserved).

(d) The license will be issued to the owner of a facility and will indicate the name and address of the facility, **the name and address of the owner of the facility**, the number [and types] of beds authorized and the date of the valid license.

(e) ~~A regular license will be issued when, in the judgment of the Department, there is substantial compliance with this subpart. (RESERVED).~~

(f) [A provisional license is governed by the following:

(1) A provisional license will be issued if there are numerous deficiencies or a serious specific deficiency and if the facility is not in substantial compliance with this subpart and the Department finds that:

(i) The applicant is taking appropriate steps to correct the deficiencies in accordance with a timetable submitted by the applicant and agreed upon by the Department.

(ii) There is no cyclical pattern of deficiencies over a period of 2 or more years.

(2) The provisional license will be issued for a specified period of time not more than 6 months. The provisional license may be renewed, at the discretion of the Department, no

more than three times. Upon substantial compliance with this subpart, a regular license will be issued.] (Reserved).

(g) [The facility shall have on file the most recent inspection reports, relating to the health and safety of residents, indicating compliance with applicable State and local statutes and regulations. Upon request, the facility shall make the most recent report available to interested persons.] (Reserved).

(h) [If the Department's inspection report indicates deficiencies, the facility shall indicate in writing its plans to make corrections and specify dates by which the corrective measures will be completed. The plans are valid only upon approval by the Department.] (Reserved).

(i) [The current license shall be displayed in a public and conspicuous place in the facility.] (Reserved).

§ 201.13a. License renewal.

~~—(a) A facility shall apply to renew its license on a form prescribed by the Department with the fee required under section 807(b) of the act (35 P.S. § 807(b)).~~

~~—(b) The Department will renew a license to operate a facility after a survey is conducted by the Department that indicates the facility is in substantial compliance with section 808(a) of the act (35 P.S. § 448.808(a)) and this subpart.~~

§ 201.13a. REGULAR LICENSE.

THE DEPARTMENT WILL ISSUE A REGULAR ONE-YEAR LICENSE WHEN THE FACILITY IS IN FULL COMPLIANCE WITH SECTION 808 OF THE ACT (35 P.S. § 448.808) AND IS IN FULL OR SUBSTANTIAL COMPLIANCE WITH THE PROVISIONS OF THIS SUBPART.

§ 201.13b. PROVISIONAL LICENSE.

(A) UNDER SECTION 812 OF THE ACT (35 P.S. § 448.812), THE DEPARTMENT MAY ISSUE A PROVISIONAL LICENSE IF THERE ARE NUMEROUS DEFICIENCIES OR A SERIOUS SPECIFIC DEFICIENCY AND THE FACILITY IS NOT IN SUBSTANTIAL COMPLIANCE WITH THIS SUBPART AND THE DEPARTMENT FINDS THAT:

(1) THE FACILITY IS TAKING APPROPRIATE STEPS TO CORRECT THE DEFICIENCIES IN ACCORDANCE WITH A TIMETABLE SUBMITTED BY THE FACILITY AND AGREED UPON BY THE DEPARTMENT.

(2) THERE IS NO CYCLICAL PATTERN OF DEFICIENCIES OVER A PERIOD OF 2 OR MORE YEARS.

(B) A PROVISIONAL LICENSE WILL BE ISSUED FOR A SPECIFIED TIME PERIOD OF NO MORE THAN 6 MONTHS.

(C) UPON A DETERMINATION OF SUBSTANTIAL COMPLIANCE, INCLUDING THE PAYMENT OF ANY FINES AND FEES, A REGULAR LICENSE WILL BE ISSUED.

§ 201.13c. LICENSE RENEWAL.

(A) A FACILITY SHALL APPLY TO RENEW ITS LICENSE ON A FORM PRESCRIBED BY THE DEPARTMENT WITH THE FEE REQUIRED UNDER SECTION 807(B) OF THE ACT (35 P.S. § 448.807(B)).

(B) IN ADDITION TO THE APPLICATION FORM AND FEE UNDER SUBSECTION (A), A FACILITY SHALL SUBMIT AN UPDATED ANNUAL FINANCIAL REPORT THAT MEETS THE REQUIREMENTS SET FORTH IN § 201.12(B)(8) (RELATING TO APPLICATION FOR LICENSE OF A NEW FACILITY OR CHANGE IN OWNERSHIP).

(C) A FACILITY SHALL FILE AN APPLICATION TO RENEW ITS LICENSE AND THE UPDATED FINANCIAL REPORT AT LEAST 21 DAYS BEFORE THE EXPIRATION OF THE CURRENT LICENSE, UNLESS OTHERWISE DIRECTED BY THE DEPARTMENT.

(D) THE DEPARTMENT WILL RENEW A REGULAR ONE-YEAR LICENSE UNDER THIS SECTION IF THE FACILITY IS IN FULL COMPLIANCE WITH SECTION 808 OF THE ACT (35 P. S. § 448.808) AND IS IN FULL OR SUBSTANTIAL COMPLIANCE WITH THE PROVISIONS OF THIS SUBPART.

(E) A PROVISIONAL LICENSE ISSUED IN ACCORDANCE WITH SECTION 812 OF THE ACT (35 P.S. § 448.812) AND § 201.13B (RELATING TO PROVISIONAL LICENSE) MAY BE RENEWED, NO MORE THAN THREE TIMES AT THE DISCRETION OF THE DEPARTMENT.

§ 201.14. Responsibility of licensee.

(a) The licensee is responsible for meeting the minimum standards for the operation of a facility as set forth by the Department and by other **Federal**, State and local agencies responsible for the health and welfare of residents. **This includes complying with all applicable Federal and State laws, and rules, regulations and orders issued by THE DEPARTMENT AND OTHER Federal, State or local agencies.**

(b) If [the] services are purchased for the administration or management of the facility, the licensee is responsible for [insuring] **ensuring** compliance with [this subpart, and other relevant Commonwealth regulations] **all applicable Federal and State laws, and rules, regulations and orders issued by the Department and other Federal, State and local agencies.**

(c) The licensee through the administrator shall report AS SOON AS POSSIBLE, OR, AT THE LATEST, **within 24 hours** to the appropriate Division of Nursing Care Facilities field office serious incidents involving residents[. As] **as** set forth in § 51.3 (relating to notification). For purposes of this subpart, references to patients in § 51.3 include references to residents.

(d) **[In addition to the notification requirements in § 51.3, the facility shall report in writing to the appropriate division of nursing care facilities field office:**

(1) Transfers to hospitals as a result of injuries or accidents.

(2) Admissions to hospitals as a result of injuries or accidents.] (Reserved).

(e) [The administrator shall notify the appropriate division of nursing care facilities field office as soon as possible, or, at the latest, within 24 hours of the incidents listed in § 51.3 and subsection (d).] (Reserved).

(f) Upon receipt of a strike notice, the licensee or administrator shall promptly notify the appropriate Division of Nursing Care Facilities field office, AND THE OFFICE OF THE STATE LONG-TERM CARE OMBUDSMAN, and keep the Department apprised of the strike status and the measures being taken to provide resident care during the strike.

(g) A facility owner shall pay in a timely manner bills incurred in the operation of a facility that are not in dispute and that are for services without which the resident's health and safety are jeopardized.

(h) The facility shall report to the Department[, on forms issued by the Department,] census, rate [and], program occupancy **and any other** information [as] the Department may request. THE DEPARTMENT WILL PROVIDE ADVANCE NOTICE OF NEW REPORTING REQUIREMENTS, EXCEPT IN INSTANCES OF AN EMERGENCY.

(i) The facility shall have on file the most recent inspection reports, relating to the health and safety of residents, indicating compliance with applicable Federal, State and local statutes and regulations. Upon request, the facility shall make the most recent report available to interested persons.

(j) The facility shall conduct a facility-wide assessment that meets the requirements of 42 CFR 483.70(e) (relating to administration), as necessary, but at least quarterly.

§ 201.15. Restrictions on license.

(a) **[A license shall apply only to the licensure, the name of the facility and the premises designated therein. It may not be transferrable to another licensee or property without prior written approval of the Department.] (Reserved).**

(b) A license becomes **automatically** void without notice if any of the following conditions exist:

(1) The [expiration date has been reached] license term expires UNLESS THE TERM EXPIRES DUE TO A DEPARTMENTAL DELAY, A FEDERAL EMERGENCY OR STATE DISASTER EMERGENCY.

- (2) There is a change in ownership and the Department has not given prior approval.
- (3) There is a change in the name of the facility, and the Department has not given prior approval **[for the transfer of the license]**.
- (4) There is a change in the location of the facility and the Department has not given prior approval.

(c) ~~A final order or determination by the Department relating to licensure may be appealed by the provider of services to the Health Policy Board under section 2102(n) of The Administrative Code of 1929 (71 P.S. § 532(n)).~~ (RESERVED).

§ 201.15a. ENFORCEMENT.

ACTIONS THE DEPARTMENT MAY TAKE TO ENFORCE COMPLIANCE WITH THE ACT AND THIS SUBPART INCLUDE BUT ARE NOT LIMITED TO THE FOLLOWING:

- (a) REQUIRING A PLAN OF CORRECTION.
- (b) ISSUANCE OF A PROVISIONAL LICENSE.
- (c) LICENSE REVOCATION.
- (d) APPOINTMENT OF A TEMPORARY MANAGER.
- (e) LIMITATION OR SUSPENSION OF ADMISSIONS TO THE FACILITY.
- (f) ASSESSMENT OF FINES OR CIVIL MONETARY PENALTIES.

§ 201.15b. APPEALS.

A FINAL ORDER OR DETERMINATION OF THE DEPARTMENT RELATING TO LICENSURE MAY BE APPEALED BY THE PROVIDER OF SERVICES TO THE HEALTH POLICY BOARD UNDER SECTION 2102(n) OF THE ADMINISTRATIVE CODE OF 1929 (71 P.S. § 532(n)).

* * *

§ 201.17. Location.

[The facility shall be operated as a unit reasonably distinct from the other related services, if located in a building which offers various levels of health-related services.] With the approval of the Department, a facility may be located in a building that offers other health-related services, such as personal care, home health or hospice services, and may share services such as laundry, pharmacy and meal preparations. The facility shall be

~~operated as a unit distinct from other health-related services~~ WITH OTHER PROVIDERS

AND SHARE SERVICES AS FOLLOWS:

(1) THE PROVIDER IS LICENSED, AS APPLICABLE.

(2) THE PROVIDER OPERATES OR PROVIDES OTHER HEALTH-RELATED SERVICES, SUCH AS PERSONAL CARE, HOME HEALTH OR HOSPICE SERVICES.

(3) THE SHARED SERVICES MAY INCLUDE SERVICES SUCH AS LAUNDRY, PHARMACY AND MEAL PREPARATIONS.

(4) THE FACILITY SHALL BE OPERATED AS A UNIT DISTINCT FROM OTHER HEALTH-RELATED SERVICES.

* * *

§ 201.22. Prevention, control and surveillance of tuberculosis (TB).

(a) The facility shall have a written TB infection control plan with established protocols which address risk assessment and management, screening and surveillance methods, identification, evaluation, and treatment of residents and [employees] employees who have a possible TB infection or active TB.

(b) Recommendations of the Centers for Disease Control and Prevention (CDC), United States Department of Health and Human Services (HHS) shall be followed in screening, testing and surveillance for TB and in treating and managing persons with confirmed or suspected TB.

(c) [A baseline TB status shall be obtained on all residents and employees in the facility.] (Reserved).

(d) [The intradermal tuberculin skin test is to be used whenever skin testing is done. This consists of an intradermal injection of 0.1 ml of purified protein derivative (PPD) tuberculin containing 5 tuberculin units (TU) using a disposable tuberculin syringe.] (Reserved).

(e) [The 2-step intradermal tuberculin skin test shall be the method used for initial testing of residents and employees. If the first test is positive, the person tested shall be considered to be infected. If the first test is negative, a second test should be administered in 1—3 weeks. If the second test is positive, the person tested shall be considered to be previously infected. If the second test result is negative, the person is to be classified as uninfected.] (Reserved).

(f) [Persons with reactions of ≥ 10 mm or persons with symptoms suggestive of TB regardless of the size of the test reaction, shall be referred for further diagnostic studies in accordance with CDC recommendations.] (Reserved).

- (g) [A written report of test results shall be maintained in the facility for each individual, irrespective of where the test is performed. Reactions shall be recorded in millimeters of induration, even those classified as negative. If no induration is found, "0 mm" is to be recorded.] (Reserved).
- (h) [Skin test "negative" employes having regular contact of 10 or more hours per week with residents shall have repeat tuberculin skin tests at intervals determined by the risk of transmission in the facility. The CDC protocol for conducting a TB risk assessment in a health care facility shall be used to establish the risk of transmission.] (Reserved).
- (i) [Repeat skin tests shall be required for tuberculin-negative employes and residents after any suspected exposure to a documented case of active TB.] (Reserved).
- (j) [New employes shall have the 2-step intradermal skin test before beginning employment unless there is documentation of a previous positive skin reaction. Test results shall be made available prior to assumption of job responsibilities. CDC guidelines shall be followed with regard to repeat periodic testing of all employes.] (Reserved).
- (k) [The intradermal tuberculin skin test shall be administered to new residents upon admission, unless there is documentation of a previous positive test.] (Reserved).
- (l) [New tuberculin positive reactors (converters) and persons with documentation of a previous positive reaction, shall be referred for further diagnostic testing and treatment in accordance with current standards of practice.] (Reserved).
- (m) [If an employe's chest X-ray is compatible with active TB, the individual shall be excluded from the workplace until a diagnosis of active TB is ruled out or a diagnosis of active TB is established and a determination made that the individual is considered to be noninfectious. A statement from a physician stating the individual is noninfectious shall be required.] (Reserved).
- (n) [A resident with a diagnosis of TB may be admitted to the facility if:
- (1) Three consecutive daily sputum smears have been negative for acid-fast bacilli.
 - (2) The individual has received appropriate treatment for at least 2-3 weeks.
 - (3) Clinical response to therapy, as documented by a physician, has been favorable.] (Reserved).

* * *

CHAPTER 209. FIRE PROTECTION AND SAFETY PROGRAMS FOR LONG-TERM CARE NURSING FACILITIES.

FIRE PROTECTION AND SAFETY

§ 209.1. [Fire department service] (Reserved).

[The telephone number of the emergency services serving the facility shall be posted by the telephones in each nursing station, office and appropriate place within the facility.]

*** * ***

§ 209.7. [Disaster preparedness] (Reserved).

[(a) The facility shall have a comprehensive written disaster plan which shall be developed and maintained with the assistance of qualified fire, safety and other appropriate experts. It shall include procedures for prompt transfer of casualties and records, instructions regarding the location and use of alarm systems and signals and fire fighting equipment, information regarding methods of containing fire, procedures for notification of appropriate persons and specifications of evacuation routes and procedures. The written plan shall be made available to and reviewed with personnel, and it shall be available at each nursing station and in each department. The plan shall be reviewed periodically to determine its effectiveness.

(b) A diagram of each floor showing corridors, line of travel, exit doors and location of the fire extinguishers and pull signals shall be posted on each floor in view of residents and personnel.

(c) All personnel shall be instructed in the operation of the various types of fire extinguishers used in the facility.]

§ 209.8. [Fire drills] (Reserved).

[(a) Fire drills shall be held monthly. Fire drills shall be held at least four times per year per shift at unspecified hours of the day and night.

(b) A written report shall be maintained of each fire drill which includes date, time required for evacuation or relocation, number of residents evacuated or moved to another location and number of personnel participating in a fire drill.]

**CHAPTER 211. PROGRAM STANDARDS FOR LONG-TERM CARE
NURSING FACILITIES.**

§ 211.1. Reportable diseases.

(a) When a resident develops a reportable disease, the administrator shall report the information to the appropriate health agencies and appropriate Division of Nursing Care Facilities field office. Reportable diseases, infections and conditions are listed in § 27.21a (relating to reporting of cases by health care practitioners and health care facilities).

(b) Cases of scabies [and] or lice or bed bug infestations shall be reported to the appropriate Division of Nursing Care Facilities field office.

(c) Significant nosocomial outbreaks, as determined by the facility's medical director, Methicillin Resistant Staphylococcus Aureus (MRSA), Vancomycin-Resistant Staphylococcus Aureus (VRSA), Vancomycin-Resistant Enterococci (VRE) and Vancomycin-Resistant Staphylococcus Epidermidis (VRSE) shall be reported to the appropriate Division of Nursing Care Facilities field office.

* * *

From: Bradbury, Joan
To: Smith, Pamela (Health); Brooks, Senator Michele
Subject: RE: Final-Form Long-Term Care Nursing Facility Regulations - Rulemaking 3 (10-223)
Date: Tuesday, September 27, 2022 9:49:44 AM

Received, thank you Pam.

Joan Bradbury
Executive Director
Senate Health & Human Services Committee
717-787-1475 (direct)

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SEP 27 2022

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Review Commission

From: Smith, Pamela (Health) <pamesmith@pa.gov>
Sent: Tuesday, September 27, 2022 8:23 AM
To: Brooks, Senator Michele <mbrooks@pasen.gov>
Cc: Bradbury, Joan <jbradbury@pasen.gov>
Subject: Final-Form Long-Term Care Nursing Facility Regulations - Rulemaking 3 (10-223)
Importance: High

ⓘ CAUTION : External Email ⓘ

Good morning,

Attached are final-form long-term care nursing facility regulations – rulemaking 3 (10-223) from the Department of Health. This is the third of four long-term care nursing facility packages that are being delivered to you today.

Under the Regulatory Review Act, the Department is required to deliver a final-form regulatory package to the Standing Committees of the General Assembly and the Independent Regulatory Review Commission (IRRC) **on the same day**, with IRRC receiving the package last. Confirmation of receipt by the Standing Committees is required for delivery to IRRC.

Please respond as soon as possible to this email indicating that you have received the attached final-form regulatory package so that I can deliver the package to IRRC **today, September 27, 2022**.

Thanks,
Pam

Pamela G. Smith | Assistant Counsel
Pennsylvania Department of Health | Office of Legal Counsel
625 Forster Street | Harrisburg, PA 17120 - 0701
Phone: 717.783.2500 | Fax: 717.705.6042
www.health.state.pa.us

From: Fricke, Erika L.
To: Smith, Pamela (Health); Frankel, Dan
Subject: RE: Final-Form Long-Term Care Nursing Facility Regulations - Rulemaking 3 (10-223)
Date: Tuesday, September 27, 2022 10:46:15 AM

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From: Smith, Pamela (Health) <pamesmith@pa.gov>
Sent: Tuesday, September 27, 2022 8:24 AM
To: Frankel, Dan <DFrankel@pahouse.net>
Cc: Fricke, Erika L. <EFricke@pahouse.net>
Subject: Final-Form Long-Term Care Nursing Facility Regulations - Rulemaking 3 (10-223)
Importance: High

**Independent Regulatory
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From: Freeman, Clarissa
To: Smith, Pamela (Health)
Subject: Re: Final-Form Long-Term Care Nursing Facility Regulations - Rulemaking 3 (10-223)
Date: Tuesday, September 27, 2022 9:27:01 AM

Received.
Thank you,
Clarissa

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SEP 27 2022

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From: Smith, Pamela (Health) <pamesmith@pa.gov>
Sent: Tuesday, September 27, 2022 8:24:59 AM
To: Haywood, Senator Art <art.haywood@pasenate.com>
Cc: Freeman, Clarissa <clarissa.freeman@pasenate.com>
Subject: Final-Form Long-Term Care Nursing Facility Regulations - Rulemaking 3 (10-223)

■ EXTERNAL EMAIL ■

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From: Michael Siget
To: Smith, Pamela (Health); Kathy Rapp
Subject: RE: Final-Form Long-Term Care Nursing Facility Regulations - Rulemaking 3 (10-223)
Date: Tuesday, September 27, 2022 8:36:34 AM

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SEP 27 2022

From: Smith, Pamela (Health) <pamesmith@pa.gov>
Sent: Tuesday, September 27, 2022 8:22 AM
To: Kathy Rapp <Klrapp@pahousegop.com>
Cc: Michael Siget <Msiget@pahousegop.com>
Subject: Final-Form Long-Term Care Nursing Facility Regulations - Rulemaking 3 (10-223)
Importance: High

Independent Regulatory
Review Commission

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